

EXHIBIT F

1 REPORTER'S RECORD

2 VOLUME OF VOLUMES

3 TRIAL COURT CAUSE NO. DC-12-14350

4 LINDA BATISTE (IN THE DISTRICT COURT
vs.
5 JOHN ROBERT MCNABB, M.D., (DALLAS COUNTY, TEXAS
JOHNSON & JOHNSON, AND
6 ETHICON, INC. (95TH JUDICIAL DISTRICT

11 _____
12 TRIAL PROCEEDINGS
13 _____
14

18 On the 28th day of March, 2014, the following
19 proceedings came on to be held in the above-titled and
20 numbered cause before the Honorable, Judge Ken Molberg
21 Presiding, held in Dallas, Dallas County, Texas.

22 Proceedings reported by computerized
23 stenotype machine.

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1 P R O C E E D I N G S

2 (Jury Out)

3 MR. GAGE: Good afternoon, Your Honor.

4 THE COURT: How are you?

5 MR. GAGE: Good. One, pursuant to the
6 side-bar that we had during Dr. Hinoul's examination, I
7 have a very short proffer to make, and then I have no
8 further questions of the witness. But given that we
9 need to get Dr. Thames on and off the stand today, I
10 discussed this with Mr. Cartmell, and he is agreeable
11 if it's agreeable with Your Honor that on Monday I
12 would make the proffer, if Your Honor is okay with
13 that. And then also on Monday, Mr. Cartmell and I
14 would each introduce the exhibits on the record that we
15 used with the witness.

16 THE COURT: That's fine with me.

17 MR. CARTMELL: Fine with me.

18 THE COURT: How are y'all going to get
19 him on and off today?

20 MR. GAGE: We can do it.

21 THE COURT: I'm going to let the Jury go
22 a little bit earlier.

23 MR. CARTMELL: We're shooting for four.
24 Were you are thinking 3:30? We can maybe do that.

25 MR. NOTEWARE: I'll see if I can pare it

1 down. We'll just go as quickly as we can.

2 Dr. Hinoul, we're not going to ask any more
3 questions. We would like for him to be released, Your
4 Honor.

5 MR. CARTMELL: Well, now, that's a whole
6 other issue. I'm kidding. We agree.

7 MR. CAPSHAW: No objection, Your Honor.

8 MR. CARTMELL: No objection.

9 THE COURT: All right, sheriff, line
10 them up.

11 (In Presence and Hearing of the Jury)

12 THE COURT: Be seated. Please. The
13 Defendants may call their next witness.

14 MR. NOTEWARE: Your Honor, defense will
15 call Dr. Shelby Thames.

16 (Witness sworn)

17 DR. SHELBY THAMES,
18 having been sworn, testified as follows:

19 DIRECT EXAMINATION

20 Q. State your name for the record, please, sir?

21 A. Shelby Freeland Thames, T-h-a-m-e-s.

22 Q. Where do you live, Dr. Thames?

23 A. I live in Hattiesburg, Mississippi.

24 Q. I am calling you a doctor, you are a doctor,
25 are you not?

1 A. I have a Ph.D., yes, sir.

2 Q. Let's talk about -- you're are not a medical
3 doctor?

4 A. I am not a medical doctor.

5 Q. Let's talk about what your academic
6 credentials are, please?

7 A. All right.

8 Q. Where did you do your undergraduate work?

9 A. University of Southern Mississippi.

10 Q. And you have a degree?

11 A. Yes, sir, in chemistry.

12 Q. Then?

13 A. A masters degree in chemistry from Southern
14 Miss, Ph.D. in chemistry, organic chemistry, and
15 analytical chemistry from the University of Tennessee.

16 Q. And you got that Ph.D. in that year, please?

17 A. 1964.

18 Q. Did you get full-time employment thereafter?

19 A. I sure did.

20 Q. And where did you go to work?

21 A. University of Southern Mississippi, 52 years
22 ago.

23 Q. And in what capacity did you start at
24 Southern Miss?

25 A. As an Assistant Professor of Chemistry.

1 Q. Tell the Jury, if you would, please, go
2 through the various positions, then that you've held
3 at -- well, are you still at Southern Miss?

4 A. I am, sir.

5 Q. All right. Tell the Jury your various
6 positions that you've held at Southern Miss during this
7 period of time?

8 A. I have been an Assistant Professor, excuse
9 me, before that an instructor, an Assistant Professor,
10 Associate Professor, full professor, a Dean, Vice
11 President, Executive Vice President, President of the
12 University and now Distinguished University Research
13 Professor.

14 Q. You were actually President of the University
15 for a period of time?

16 A. Yes, for five years.

17 Q. And you're still there?

18 A. Yes, sir.

19 Q. Still working there?

20 A. Yes, sir, I am.

21 Q. And let's put up on the screen, if you would,
22 please, Jamey.

23 Where do you work, in what building?

24 A. In the Polymer Science Research Center, sir.

25 Q. And what's the name of the Polymer Science

1 Research Center? What is the name on the building?

2 A. Shelby Freland Thames Polymer Science

3 Research Center.

4 Q. Why is your name up there on that building?

5 A. They had to put somebody's name up there.

6 Q. Who is the one that started the department?

7 A. I did.

8 Q. It wasn't there before you got there?

9 A. No, sir, it was not.

10 Q. What would you say your profession is then?

11 A. Well, I'm a polymer scientist. I'm a
12 coatings expert, I've been involved in the coatings
13 arena since 1964.

14 Q. Let's tell the Jury what a polymer scientist
15 is, to begin with.

16 A. Well, the way I like to describe it is that a
17 polymer scientist is a molecular architect, much as an
18 architect will design a building for a specific
19 purpose, a polymer scientist will design a molecule for
20 a specific purpose.

21 That's about the best I can do, sir.

22 Q. That's good enough.

23 A. All right.

24 Q. You indicated that you have a specialty
25 within polymer science?

1 A. That's correct.

2 Q. What is that specialty?

3 A. My specialty is in coatings. And
4 everything --

5 Q. What do you mean by coatings?

6 A. Well, most everything is coated. For
7 instance, the glasses I have on have a coating, any of
8 those wearing glasses. Contact lens have coatings.
9 Coatings on top of this glass. Coatings on the light
10 fibers, on automobiles. On almost everything you
11 touch, see and use has a coating on it. The one thing
12 that a coating must have is, that it must adhere, stick
13 to a surface. If it doesn't stick to the surface and
14 adhere tenaciously, it's not a coating, it's something
15 else.

16 Q. That's been your subspecialty, your specialty
17 within polymer science, sir?

18 A. That's correct, sir.

19 Q. Have you received any honors during the
20 course of your career?

21 A. A few.

22 Q. All right. Were you ever named the, let's
23 put that on the board, the Coating R&D Person of the
24 Year?

25 A. Yes, sir, I was.

1 Q. Have you published any articles?

2 A. Yes, I have.

3 Q. Tell the Jury about the kind of articles you
4 published, and the numbers of articles that you
5 published?

6 A. In my profession you do research, you look at
7 different kinds of chemistry and you uncover knowledge
8 that people have not uncovered and you publish those in
9 manuscripts or journal articles. And I have published
10 approximately 160 manuscripts.

11 Q. How about presentations, have you made any
12 presentations?

13 A. Yes, sir, I have.

14 Q. About how many?

15 A. Approximately 160 as well.

16 Q. Let me hand you a copy of what has been
17 marked as Defendant's Exhibit 10739 and ask you if you
18 could identify that for us, please.

19 A. Yes, sir, I can.

20 Q. What is this?

21 A. That's my curriculum vitae. It talks about
22 what I've done over the last several years.

23 Q. And these are all the presentations and the
24 articles and this kind of stuff that you've done over
25 these years?

1 A. Yes, sir.

2 MR. NOTEWARE: Your Honor, we would
3 offer then Exhibit 10739 into evidence.

4 THE COURT: Any objection?

5 MR. CARTMELL: No objection, Your Honor.

6 THE COURT: Admitted.

7 Q. Have you been a teacher during the course of
8 your career?

9 A. Yes, sir.

10 Q. And taught what levels of students?

11 A. I've taught undergraduate students at the
12 baccalaureate level, at the masters level, at the Ph.D.
13 level. Also we have individuals who have obtained a
14 Ph.D. who come to our institution who want to know
15 about a field, in this particular case polymer science,
16 they're called postdoctoral fellows and we have those
17 in our group and we do research as well.

18 Q. Do you do research?

19 A. Absolutely.

20 Q. What kind of research have you done, sir?

21 A. Well, I'll tell you a couple of them that's
22 most recent. Most recent, my group has developed a soy
23 protein adhesive that is to replace formaldehyde.
24 Formaldehyde is a toxic agent and it's used in
25 particleboards to adhere the fibers of boards together

1 such as medium density fiberboard and wallboard and
2 things of that type. We developed a soy protein fine
3 adhesive to replace that. We're in the process of
4 commercializing it now.

5 We've also developed some vegetable oil macro
6 chemistry, macro technology chemistry in which we're
7 using vegetable oil in waterborne latex paints that
8 have no odor at all. You could be painting in this
9 courtroom and you wouldn't know it unless you saw the
10 individual doing it. You would never smell it.

11 Those are two of the most current things
12 we're dealing with and those are patented processes.

13 Q. You hold multiple patents?

14 A. Yes, sir.

15 Q. Now, this case is about mesh made from
16 polypropylene.

17 A. Yes, sir.

18 Q. Have you ever specifically studied
19 polypropylene before you got involved in this mesh
20 litigation?

21 A. I've not done research on polypropylene.
22 I've taught polypropylene in my classes as a
23 thermoplastic polymer. There are two general
24 categories of polymers, a thermosetting, meaning if you
25 heat them they will set, become hard; and then

1 thermoplastic, meaning if you will heat them they would
2 become ductile and moldable. Then when you cool them,
3 they'll stay in that shape. So polypropylene is a
4 thermoplastic material.

5 Q. Do you feel then that your training and
6 education, your experience has taught you to be able to
7 be here before this Jury as an expert to talk about
8 polypropylene?

9 A. Yes, sir, I do.

10 Q. And its characteristics, and its degradation,
11 its deterioration or oxidation of it?

12 A. Yes, sir, I do.

13 Q. When you approached this project -- first of
14 all, have you looked at other polymers? Is
15 polypropylene a polymer?

16 A. Absolutely.

17 Q. Have you looked at other polymers to do the
18 same kind of work with that you've done in this case?

19 A. Hundreds of them.

20 Q. Did you use the same methodology in other
21 instances that you used in this case?

22 A. Yes, sir.

23 Q. I just said that polypropylene is a polymer.

24 A. Yes, sir.

25 Q. What is a polymer?

1 A. Well, if we break the word down, polymer,
2 it's p-o-l-y-m-e-r. Poly means many, and mer means
3 single units. And the way I like to explain that is if
4 you talk about a chain, any kind of chain that you
5 might have that has links in it.

6 Each of the links would be a mer unit. As
7 you enhance those links and you hook them together, you
8 can build a longer and longer chain.

9 And that, in effect, is what we do with
10 molecules. If we take one molecule, hook it to another
11 one, and hook that one to another one, another one, we
12 end up with a polymer which is many mer units.

13 So that's a polymer, big molecule s huge.
14 Molecules.

15 Q. What is polypropylene then?

16 A. Polypropylene is a large molecule made from
17 propylene, a monomer. Propylene is the monomer.

18 Q. Do you want to diagram that for us or no?

19 A. I'd be happy to.

20 MR. NOTEWARE: Is it all right, Judge,
21 if he approaches the whiteboard?

22 Q. Tell the Jury what you're going to show them
23 and then show it to them.

24 A. I'm going to show you the monomer propylene,
25 and then I'm going to show you how it's made into

1 polypropylene, and then we'll talk about that.

2 The monomer is the CH₂. Now, C is a carbon
3 atom and H is a hydrogen atom, so that's the monomer.

4 And then you -- that's -- and then you can
5 add a little heat to that and pressure and an initiator
6 and you end up with a polymer, and this is
7 polypropylene.

8 Now, the reason that I put brackets around
9 this and an X is because this goes on and on and on
10 until the size of this molecule becomes essentially
11 330,000.

12 Now, each of these individual units right
13 here is a weight of 42. That's the atomic weight.
14 They have to have a weight, so it's 42. Well, if it's
15 300,000, that's about 8,000 of these that have to be in
16 a row, if my math is right, to give you the molecular
17 weight of a typical polypropylene molecule we'll be
18 talking about today. So that's a long-chain molecule
19 like so, long chain of about 330,000. Total molecular
20 weight.

21 Q. I note that you've only used C&H?

22 A. Yes, sir.

23 Q. C stands for?

24 A. C is for carbon.

25 Q. H is for?

1 A. Hydrogen.

2 Q. Now, is it somehow important that the
3 composition of polypropylene is made of only carbon and
4 hydrogen?

5 A. It gives it some distinct characteristics in
6 that if it's only carbon and hydrogen it has resistance
7 to a lot of external environmental forces that might
8 otherwise attack it.

9 For instance, if water is the most damaging
10 forces in nature, and water would attack a material
11 that was subject to hydrolysis by water, a breaking
12 apart.

13 Q. Is it called a universal solvent?

14 A. Yes, it is, water is.

15 This molecule has nothing that would indicate
16 its affinity for water. It doesn't like water. It's
17 not permeable to water. It's not soluble in water.

18 Acids and bases, typically under normal
19 conditions will not attack it. So it's inert, but it's
20 not totally inert.

21 Q. Inert means?

22 A. Inert means doesn't like to react, doesn't
23 react. But everything will react under some condition,
24 this is not a totally inert molecule, but inert with
25 regard to other chemical species.

1 Q. Okay. Great. Enough?

2 A. Yes, sir.

3 Q. Can you good back and sit down?

4 A. Yes, sir.

5 Q. I will tell you my next question so you can
6 be thinking about on the way up there.

7 What is PROLENE?

8 A. That's polypropylene, sir, isotactic
9 polypropylene. The isotactic parts means that CH₃
10 group that I've drawn up there is on the same side of
11 the molecule. If you have the long carbon chain it's
12 one right after the other, on the same side of the
13 molecule.

14 Q. So polypropylene is an isotactic polymer?

15 A. Yes, sir, it is.

16 Q. Okay.

17 A. It's isotactic polypropylene.

18 Q. Now, does the PROLENE have -- is it pure
19 polypropylene?

20 A. No, sir, not the PROLENE that's manufactured
21 by Ethicon, it is not.

22 Q. And what has been added to the polypropylene
23 to make it into PROLENE?

24 A. PROLENE is a formulated product which means
25 that there's some ingredients that have been added to

1 improve its performance properties. In the case of
2 PROLENE, it's Prokel LA, which is a flow control agent,
3 slip aid, calcium stearate, the same sort of material.
4 There's a colorant to show that it's blue, and then
5 there's two antioxidants that are added. The
6 antioxidants mean they ward off oxidation.

7 One of them is called Santonox R, and the
8 other one, get ready, is called dilauryl
9 thiiodipropionate.

10 The synonym for that is DLTDP.

11 Q. DLTDP?

12 A. Yes, sir.

13 Q. I will promise you that I ain't going to call
14 it whatever you said it was to begin with.

15 A. Thank you.

16 Q. All right. Now, tell us very quickly how
17 PROLENE is manufactured.

18 A. First thing you do is that you take propylene
19 and the reactor and there's a big vessel or reactor and
20 you add these ingredients to it, which is in this case
21 propylene and it's under heat and a little pressure.
22 Zeigler-Natta, Z-e-i-g-l-e-r N-a-t-t-a, catalyst is
23 added.

24 The reaction takes place in one molecule
25 after the other, attaches just as I've shown here,

1 until you get a very high molecular weight species of
2 in the range of 330,000. It's big, a big molecule.

3 Q. You've added the additives in as well?

4 A. Yes, sir. You take those materials that come
5 out of the reactor -- I'm sorry, I should have said
6 that it's in a solid form you take those you grind them
7 up and you put them in a hopper along with the
8 additives that I've talked about, and the hopper drops
9 into a unit with a heating vessel in it. It mixes it
10 and grinds it and heats it up, so that it's a fluid.

11 Just like taffy, hot taffy.

12 This instrument will also, under pressure
13 will push that hot fluid out through a die, and that's
14 the formed object that's been machined and it will come
15 out as a string, as a fiber. And we'll be talking
16 about polypropylene fibers, and that's how it's made,
17 sir.

18 Q. I'm not sure any of these jurors can
19 remember, but remember the days that you used to grind
20 hamburger at home or used to grind, I did cranberries?

21 A. I remember the hamburger days. Some of you
22 may have seen where you put your hamburger meat in the
23 top and you grind it, and it extrudes out in hamburger
24 fibers.

25 Well, this just happens to be a similar

1 approach here.

2 Q. So what we have then as PROLENE is a
3 polypropylene in a fiber form that has the additives
4 mixed in with it, is that correct?

5 A. Yes, sir, it is.

6 Q. We've gotten this far.

7 Now, let's talk about what's been talked
8 about in this case.

9 First of all, there's been a discussion of
10 degradation, in other words, deterioration of the
11 polypropylene fibers or the PROLENE fibers.

12 What does degradation days mean to you, sir?

13 A. Well, to me degradation means that there has
14 been an effect upon the product, some product, whatever
15 it is you're talking about, that will alter its ability
16 to perform its intended purpose.

17 In other words, degradation is such that it
18 just can't do what you expected it to do at the outset
19 of use.

20 Q. Dr. Jordi was here several days ago and
21 talked about three ways in which a polymer can degrade.
22 He indicated oxidation, environmental stress cracking
23 and mechanical degradation. Would you say those are
24 the three the primary methods of degradation of a
25 polymer?

1 A. Well, those are three ways. Some polymers
2 are not subject to environmental stress cracking but
3 there are three ways.

4 Q. He ruled out, however, environmental stress
5 crack, said that really wasn't an issue here, and
6 mechanical degradation. And said the only way that he
7 was going to be talking about degradation with regard
8 to PROLENE would be oxidation. Is that fair enough,
9 could we do that?

10 A. Yes, sir.

11 Q. Okay. Before we talk about oxidation,
12 though, let's talk about if you have the degradation,
13 the deterioration of the -- of the polypropylene, of
14 the PROLENE, what would you expect to find? You're
15 going to be examining some PROLENE mesh, what would you
16 expect to find?

17 A. If you have oxidation of isotactic
18 polypropylene, the material that we're talking about
19 today, there are a few things that you would be able to
20 find as a scientist.

21 Number one, you would find a reduction in
22 molecular weight. And I talked about this long chain,
23 and the molecule was 332,000. You would have -- the
24 chain would be cleaved in two, just like you took a
25 pair of scissors and snipped it in two.

1 So you would no longer have the long polymer,
2 you would have a shorter polymer. That's one thing.
3 So a loss in molecular weight would accompany
4 degradation.

5 The next thing that you would have is the
6 degradation process would be produced, more than likely
7 in the context that we're talking about, oxidation. So
8 that means that you have to add oxygen to polypropylene
9 if it oxidizes, because that is the definition of
10 oxidation is adding oxygen. You add oxygen to iron,
11 and you get iron oxide, that's rust. You add oxygen to
12 polypropylene and you will get an oxygen containing
13 derivative of polypropylene.

14 So you would expect that.

15 You would also expect that the mechanical
16 properties of polypropylene would drastically be
17 affected in a negative way.

18 For instance, if I take this long chain
19 polypropylene molecule, it has a certain strength, we
20 call tensile strength. It has a certain elongation.
21 Tensile strength is a strength, that when you begin to
22 pull the molecules, you can pull it and pull it and
23 pull it and they'll straighten out, straighten out, and
24 then finally they'll break. That's called the tensile
25 strength at which that breaks is called the ultimate

1 tensile strength. In other words, that's its strength
2 in terms of mechanic stress.

3 If you talk about how far do you have to pull
4 it before it broke, that's the elongation.

5 How far could I elongate it if I start out
6 with 1 inch of the material? Can I go to 2 inches or
7 3 inches or 4 inches, before it breaks?

8 So that's tensile strength and elongation,
9 and those two features would dramatic decline if I had
10 chain cleavage of that molecule, and I think it's easy
11 to understand. If you think about a bowl of spaghetti
12 all of us have cooked spaghetti. At my home my wife
13 takes the spaghetti she gets at the store and she
14 breaks it in two, and I asked her why do you do that.
15 She said, well, if I don't do that I get such long
16 strands that it's all entangled and I can't handle it.

17 And I said, well, why don't you try that, and
18 I challenge you to do that, when you go home take one
19 of those strands and see if you can pull it out of that
20 mass without breaking it. The answer is no. The
21 reason you can't is because all of those strands
22 intertwined, intertwined, twisted together.

23 That's what happens in polypropylene, that
24 they do that actually, and therefore, that's what gives
25 them their strength. When you begin to pull them, then

1 you elongate those strands. Instead of being wadded,
2 they begin to line up to each other, slide by each
3 other.

4 Q. I am going to stop you right there because
5 we've talked about two ways in which polypropylene
6 degrades, or that you can see manifestations of the
7 degradation of the polypropylene.

8 A. Yes, sir.

9 Q. Number one, decrease in molecular weight?

10 A. Yes, sir.

11 Q. I want to go back about that and then we'll
12 talk about this other. Let's talk about decrease in
13 molecular weight.

14 Define again for us what molecular weight is?

15 A. It's the atomic mass of each atom in the
16 species. For instance, every one of those carbon atoms
17 has an atomic mass of 12. Every hydrogen atom has an
18 atomic mass of one. And every polypropylene molecule
19 has a total mass of 42, because there's three carbons,
20 and there's -- there should be a three on that top CH.

21 Would you correct my mistake for me, please,
22 sir?

23 Q. Right here?

24 A. Yes, sir. You did real good.

25 So there's six of those, and there's three

1 carbons, there's 36, plus six is 42.

2 So every propylene molecule has atomic mass
3 of 42.

4 Q. Now, have you had a chance to review the
5 seven-year dog study that was prepared by Ethicon,
6 Inc.?

7 A. I have.

8 Q. That is Defense Exhibit 10791, counsel.

9 What was the seven-year dog study all about?

10 A. The seven-year dog study was an implantation
11 of sutures, the polypropylene sutures, in dogs, and to
12 ultimately determine their stability in the in vivo
13 environment, the flesh environment of a dog. And they,
14 after several years, they began to take these -- these
15 explants were removed, and they tested them for various
16 physical properties. And at seven years, which was the
17 final testing of the seven-year dog study, they
18 evaluated the materials, and they did an evaluation for
19 molecular weight to determine, well, is the molecular
20 weight of this polymer the same.

21 Q. I'm going to stop you right there. You're
22 going to go on and I want to talk about molecular
23 weight.

24 A. Okay.

25 Q. After they explanted the sutures from the in

1 vivo, the tissue, then they determined what the suture
2 molecular weight was as opposed to what?

3 A. The molecular weight of the original starting
4 material called the pristine polypropylene. The
5 material that had never been placed in an animal, never
6 been in use.

7 Q. All right. Let's look, then, at some of the
8 findings here with regard to the -- this dog study.

9 Here we've got -- are these two different
10 molecular weights?

11 A. Yes, sir.

12 Q. Are they multiplying, dividing doing
13 something different? How come we have two up there?

14 A. One of the molecular weights, the smaller one
15 is called number average molecular weight, and the
16 larger one is called weight average molecular weight
17 and that's just normal sort of a discussion.

18 This particular molecular weight right here
19 is the total mass of molecules divided by the number of
20 molecules. That's why it's smaller, whereas the
21 327,000 is the total mass of the molecule divided by
22 the weight average of the molecules in question.

23 And over -- but that's the two molecular
24 weight numbers that were determined for the nonused
25 pristine brand-new polypropylene.

1 Q. All right. So we've got the -- it says
2 current/old PROLENE, that's the new, and the other one
3 is the dog 1995. So we've got the M sub W is 327 for
4 the dog, and 324,000 for the pristine, and 59,00, and
5 60,000?

6 A. Yes, sir.

7 Q. Are those statistically equivalent?

8 A. Yes, sir, they are.

9 Q. And why would you say -- because if the truth
10 be known one, is higher and one is lower than the
11 pristine?

12 A. The test that's used, the gel permeation
13 chromatographs is a plus or minus 10 percent in terms
14 of its accuracy. So those numbers could go up by
15 10 percent or down by 10 percent. They're
16 extraordinarily close, I might add.

17 Q. All right. And the results then indicate no
18 degradation has taken place.

19 The second one, before I get to that, there
20 is another portion taken from the dog study?

21 A. Yes, sir.

22 Q. And are the findings essentially the same?

23 A. Yes, they are.

24 Q. Then what did the dog studies conclude with
25 regard to degradation in terms of molecular weight?

1 A. There had been no molecular weight
2 degradation of the suture that was implanted in the dog
3 after seven years of exposure in vivo in the animal.
4 No molecular degradation.

5 Q. And how is that significant, or why is that
6 significant?

7 A. Well, it's significant because it says that
8 the implantation environment in the tissue in the dog
9 did not adversely affect the polypropylene at all. In
10 other words, it was inert to the body, in regards to
11 loss of molecular weight.

12 Q. You've seen Dr. Jordi's report?

13 A. Yes, sir.

14 Q. Did Dr. Jordi do a molecular weight analysis?

15 A. He did.

16 Q. And what were his findings?

17 A. They were essentially the same as the dog
18 studies after seven years. He found no significant
19 difference in molecular weight as well.

20 Q. Okay. Let's shift to the other aspect. We
21 talked about molecular weight, now let's talk about the
22 other, the loss of tensile strength.

23 A. All right, sir.

24 Q. Let's talk about it in terms of toughness?

25 A. Okay.

1 Q. What is toughness?

2 A. Well, toughness is the area under a curve,
3 and the Jury doesn't have a curve yet to look at, that
4 is a composite of --

5 Q. How is that?

6 A. May I step down, please? Is that all right?

7 Remember, I told you about the pulling of the
8 sample and how much energy it would take, force it
9 would take to break the sample, and then how much it
10 would be elongated when it finally broke.

11 What we've done here is we've shown a
12 strong -- stress is tensile strength, that's how much
13 energy, a force it would take to break it. Strain is
14 how much it would be elongated. So one is elongation,
15 the other is the force to break the sample. You can
16 characterize polymers as strong but not tough, strong
17 and tough, or not strong and not tough.

18 Well, in the case of a curve like this, where
19 you had a lot of force going up and up, and then
20 finally it broke, you would compare that to the blue
21 line where it has longer and longer elongation, and
22 finally it broke. And finally to the green line where
23 you didn't take much force at all to stretch it and it
24 stretched farther and it broke.

25 Q. Now, there's obviously more area, more stuff

1 under the blue line than there is the other two?

2 A. That's right. If you calculate the area
3 under this curve, and the area under this curve, and
4 yet the area under this blue curve, you will see that
5 the area is much larger under the blue curve. And area
6 under the curve is a measure of toughness.

7 Q. So in this case that which is under the blue
8 would be the toughest material, if these were three
9 separate materials?

10 A. Absolutely.

11 Q. All right. Did you get data from the
12 seven-year dog study that would enable you to determine
13 what the toughness of these sutures were after they had
14 been implanted for seven years?

15 A. I did.

16 Q. And let's look at that data.

17 A. This is the data from the seven-year dog
18 study.

19 Q. We know it was at the end of seven?

20 A. Yes, sir.

21 Q. Let's look at what's in blue, because that's
22 the PROLENE molecule that we're talking about today.

23 That look like it's yellow to me?

24 A. You're right. I don't know why I said blue,
25 I guess I was thinking about that chart I was looking

1 at a moment ago.

2 Q. All right.

3 A. This happens to be from the PROLENE study.

4 This is the amount of force that it's going to take to
5 breaker this sample.

6 Q. That's why it's called breaking strength?

7 A. That's correct. After seven years.

8 Q. Okay.

9 A. And you'll notice that after seven years the
10 change from the original was 1.68 to begin with, 1.60
11 after seven. It lost 5 percent of its breaking
12 strength in seven years. 5 percent.

13 Now, in terms of the elongation, it started
14 out at zero here, so 37 percent, and after seven years
15 it was 78 percent.

16 Now, if you take those two numbers and you
17 plot them, you will get the next --

18 Q. Why don't we plot them and go to the next
19 line.

20 A. Let's do that. Here it is.

21 Now, if you'll notice year zero, these are
22 the numbers from that chart I just gave you from the
23 seven-year dog study.

24 It requires 1.68 pounds to break this sample,
25 and it elongated 37 percent. Here is your 37 percent,

1 here is your 1.68 pounds.

2 In the blue, which is the seven-year number
3 it required 1.60 pounds and it was elongated 78.

4 Now, as a test to the Jury, I want you to
5 think about which is the tougher. Remember toughness
6 is the area under the curve. It's obvious that the
7 seven-year dog polypropylene is much tougher than it
8 was when it was placed in by surgery into the dog.

9 Q. Let's go back to those numbers, however.

10 A. Okay.

11 Q. Because there were -- you talked about two of
12 them. You talked about the breaking strength, and you
13 talked about elongation; but there is yet a third set
14 of numbers, and that's called the Young's modulus?

15 A. Yes.

16 Q. What is the Young's modulus? How does this
17 fit into this? Is it consistent, inconsistent?

18 A. Very consistent because modulus is stiffness,
19 how stiff is something and the stiffer a material is,
20 the higher the number is going to be. You see it lost
21 70 percent of its stiffness in seven years.

22 Now, you think about this, it got more
23 elastic in seven years; therefore, it was less stiff or
24 more pliable. That's completely consistent with the
25 data.

1 Q. All right. The Jury just heard this morning
2 talking about mesh needing to be elastic, is this
3 indicative of the fact that the mesh over these seven
4 years has become more elastic when it is tested for,
5 under the Young's modulus, whatever that is?

6 A. Yes, it is.

7 Q. Is the increase in elasticity, is that
8 something like plasticization?

9 A. Yes, sir.

10 Q. And that's another new term, what does that
11 mean?

12 A. Well, if you plasticize something, you make
13 it more pliable.

14 All of us have done work in the yard and
15 things like that and our hands have dried out. They've
16 gotten dry and the skin cracked. First thing you do
17 when the hands begin to dry out, you go to the lotion
18 bottle rub, and you rub the lotion on your hands and
19 your hands feel so much softer after you've done that.
20 What's happened is the lotion that you have used has
21 soaked into your skin and it has allowed your skin
22 fibers to slide by each other, and therefore, it's
23 increased the elongation of your hand.

24 It's actually increased the toughness of your
25 hand now because you've got a tougher hand, won't have

1 a tendency to crack.

2 If you didn't do that, your skin would crack
3 which would mean it wasn't tough.

4 Q. Okay. Is there any evidence then, that can
5 be gleaned from the -- this dog study and looking at it
6 in terms of molecular weight and looking at it in items
7 of tensile strength that would say that there was any
8 degradation whatsoever of these sutures during this
9 seven years that they were implanted in tissue?

10 A. No, sir. Not only did it not deteriorate, it
11 actually got better. As you can see from the toughness
12 slide that we pointed out here, it became a tougher
13 material after the implantation.

14 Q. If we don't have the bad results from
15 degradation, Dr. Jordi said the way in which you would
16 find degradation the cause for degradation would be
17 oxidation.

18 So let's talk about, then, whether or not
19 there is any evidence that there was, in fact,
20 oxidation of the tissue that was taken from
21 Ms. Batiste, okay?

22 A. Yes, sir.

23 Q. Can polypropylene or PROLENE -- let's say
24 polypropylene, I better say that.

25 A. Yes, sir.

1 Q. Can polypropylene degrade?

2 A. Yes. Polypropylene is the product that
3 doesn't have any additives to it, right?

4 Q. Right.

5 A. Yes, it will degrade.

6 Q. If you have -- is that when the polypropylene
7 would be oxidized, is that what you would call it?

8 A. Yes, sir.

9 Q. Would it be helpful for you to tell the Jury
10 or show the Jury what an oxidized polypropylene
11 molecule would look like?

12 A. It would be for me, if they don't mind.

13 Q. All right. What are you going to show us?

14 A. I'm going to draw a molecule and show you the
15 oxidation of it. A molecule is going to be a
16 polypropylene. Okay.

17 Remember, I put the brackets around here
18 because this molecule goes on and on and on, I'm just
19 going to put one segment out of that.

20 So if something oxidizes, it adds oxygen.

21 And oxygen can exist in two forms. It can exist in the
22 form that we would normally see it here or we can show
23 it by having two pair of electrons.

24 If I take that molecule and put it with this
25 molecule, I can under certain conditions do this. And

1 produce this radical, and I can take that hydrogen that
2 I just pulled off of here and bond it to that oxygen.

3 So I've abstracted a hydrogen. I've bonded
4 it here. Now, this is called the hydroperoxide. That
5 can come -- and there are many reactions that can take
6 place, I'm just showing you some of what can happen.

7 This can bond right here, now, these two form
8 a bond, so now they're bonded together.

9 Then what can happen is one of these
10 electrons can move this way, the other electron can
11 move this way, and what we then will have is a species.
12 Instead of redrawing this whole thing over, I'm going
13 to modify this. And one of these electrons has got to
14 come down here, and one will be left here. And I'll
15 show you the result of just this unit in here.

16 CH₂, CH₃, C double bond O, CH₂ with a
17 radical, C, CH₃, H. Like so.

18 Now, what I've done is I've taken this long
19 chain polypropylene, I've added oxygen under certain
20 conditions. I formed a hydroperoxide. I've extracted
21 a hydrogen, and I've cleaved the molecule. I've
22 reduced, I've taken a pair of scissors and I've cleaved
23 it. I've cut it in two. I've reduced its molecular
24 weight. If I reduce its molecular weight, I'm going to
25 generate a polymer that has less tensile strength, less

1 elongation, and less toughness.

2 But what we will see, if we've actually done
3 that is the presence of that particular group which is
4 called a carbonyl group.

5 Q. We'll get to that in a minute.

6 A. All right.

7 Q. You have indicated that polypropylene can be
8 oxidized.

9 A. Yes, sir.

10 Q. Is this something that Ethicon recognized
11 before they started creating their PROLENE mesh?

12 A. Absolutely.

13 Q. You talked earlier about these two additives?

14 A. Yes, sir.

15 Q. And the two additives were?

16 A. Santonox R, R, and dilauryl thiodipropionate.

17 Q. And they are?

18 A. Antioxidants. They're put in there to keep
19 that from happening.

20 Q. Okay. Did you have the opportunity to exam
21 some of the explanted mesh that was taken from
22 Ms. Batiste?

23 A. Yes, I did.

24 Q. And did you examine it to determine whether
25 or not there was any oxidation present?

1 A. Yes, I did.

2 Q. And what was your conclusion after your
3 testing?

4 A. There was none of that particular species in
5 the spectra of the explant. There was no oxidation.

6 Q. No oxidation.

7 What types of testing did you use to
8 determine whether or not oxidation was present?

9 A. I performed what is called a fourier
10 transform infrared spectroscope determination. The
11 acronym is FTIR. Right here.

12 Q. All right. Are there other testing that you
13 did? Let's talk about all of the testing that you did
14 of this.

15 A. Well, we looked at the fibers under a light
16 microscope.

17 Q. Do you have a picture of that up there?

18 A. Yes, sir. The light microscope is right
19 here.

20 Q. Okay.

21 A. And then we looked at it under scanning
22 electron microscope, which is right there.

23 Q. Okay.

24 A. We then did the FTIR Fourier Unit, which is
25 here.

1 Q. Then you actually measured the fiber size?

2 A. The fiber thickness right here on the bottom
3 was measured while we had the sample in this unit right
4 here. I'm sorry, my finger is moving a little bit but
5 I can't keep it still.

6 Q. That's all right.

7 Now, where was all of this testing done?

8 A. In our laboratories in the Polymer Science
9 Research Center.

10 Q. At Southern Miss?

11 A. Yes, sir.

12 Q. You didn't have to send yours out to
13 Minnesota or to California or to somebody else to have
14 it done, you had all of the equipment there?

15 A. Yes, sir.

16 Q. Okay. What product did you actually test?
17 Describe to the Jury, tell the Jury what it is you
18 actually tested?

19 A. We received a sample of the explant that was
20 taken from Ms. Batiste and took that particular product
21 and cleaned it, had it cleaned as best we could.
22 Cleaned the material that was on the fiber from it, and
23 then used that to do the light microscopy, and the
24 scanning electron microscopy, and the FTIR, and the
25 fiber thickness.

1 Q. Did you have what you earlier referred to as
2 a pristine piece of mesh?

3 A. We did.

4 Q. That would be something as if it were just
5 taken in the operating room, nothing done to it at all?

6 A. Right. And we -- we took the pristine piece
7 of mesh and we sent it through the same cleaning
8 process that the explant sample was sent through to
9 make certain that if the cleaning process had an effect
10 upon the mesh, we would see it, and that's what we
11 refer to as the exemplar sample. It's an example,
12 exemplar.

13 Q. So you want to have apples to apples, and you
14 tried to clean the explant. So, therefore, you wanted
15 to use the same process on the pristine so that in case
16 there were some impact it would be equivalent to both,
17 is that correct?

18 A. That is correct, sir.

19 Q. Okay. Now, Dr. Jordi did something he says
20 is similar. He took a piece of pristine mesh and he
21 put it in what he called formalin, and then heated it
22 up for -- to 65 degrees centigrade for 48 hours.

23 Did you do that?

24 A. No, sir.

25 Q. And why didn't you do that?

1 A. Well, I don't really know why I would do it.
2 I put -- took the pristine sample and put it
3 formalin -- or excuse me. I ran it through the
4 process. I never put it in formalin. I ran it through
5 the cleanings process, and that was going to tell me
6 whether or not the cleaning process had anything to do
7 with determining or affecting adversely the pristine
8 sample.

9 Q. Why is it important to putted it through a
10 cleaning process? Why can't you just work with it as
11 you got it?

12 A. When a surgeon removes the explant from a
13 human body, it has tissue and flesh on it. It is very
14 common, a common practice for the surgeons to try to
15 preserve that sample. And when they do they drop it in
16 formaldehyde as a preservative, and formaldehyde will
17 react chemically with the proteins that are in the
18 flesh.

19 And when formaldehyde reacts with the
20 proteins that are in the flesh, it forms a casing
21 around the fiber. It also functions as an armor or a
22 shield. It's used by the histology people to fix the
23 fibers. It's a well known process.

24 And so if you're going to look at the
25 polypropylene fiber, you've got to get that off the

1 fiber. You've got this casing around. It's just like
2 if this is the fiber, and I have a casing or a coating
3 all the way around this, I can't examine that until I
4 remove the coating or the shield that's there.

5 Q. Is this reaction between formaldehyde and
6 protein, and tissue is protein, right?

7 A. Yes, sir. It contains protein, yes, sir.

8 Q. Is the reaction between formaldehyde and
9 protein something that's been known for years?

10 A. It was published first, first that I seen of
11 it in 1949. So this is a well known, long time
12 chemistry concept that's been well known.

13 Q. So this is nothing new, nothing exotic or
14 esoteric that you came up with?

15 A. No, sir. You see right here it was submitted
16 for publication in 1948 and it was finally published in
17 1949.

18 Q. All right. Let's talk about the reaction
19 then between the formaldehyde and the protein.

20 A. Sure.

21 Q. And this time, rather than make you come
22 down, I'll put a formula on the --

23 A. Okay.

24 Q. I don't even know what that -- would you call
25 that a formula, what is that?

1 A. Yes, sir, that's a chemical equation.

2 Q. Equation, that's the word I was looking for.

3 A. Yes, sir.

4 Q. Why don't you tell the Jury what this is all
5 about.

6 A. Here again, if you don't mind, I need to step
7 down so I can point.

8 MR. NOTEWARE: Is that okay, Judge?

9 THE COURT: Yes, sir.

10 A. What I've done here, I've shown you only a
11 very small portion of a protein molecule.

12 THE COURT: Why don't you come out here,
13 Doctor, I don't want you in that area.

14 THE WITNESS: Okay. No problem.

15 A. This is a small portion of a protein
16 molecule. This has an active hydrogen group, and this
17 is the formaldehyde molecule, very small. Carbonyl
18 this group there. What happens is this group right
19 here attacks this carbon atom, produces a hydroxyl
20 group. And then that attacks another NH and bonds two
21 protein polymers together with what is referred to as a
22 methylene group.

23 And that happens again and again and again.

24 So because you have it in the solution as
25 excess formaldehyde, and so you achieve a polymer of

1 immense molecular weight. So you've built a casing
2 around the fiber. Immense molecular weight that's
3 very, very difficult to remove.

4 Q. But you tried to remove it?

5 A. Yes, sir.

6 Q. Were you successful?

7 A. Not all of it, could not get it all off.

8 Q. But you got as much off as you could?

9 A. Yes, sir.

10 Q. Okay. You can step back up there, if you
11 would, please, to the witness stand.

12 A. All right.

13 Q. Now, did you use chemicals in an effort to
14 try to get this -- I guess this is a formaldehyde
15 hydrogen cross linked polymer, is that correct?

16 A. Well, it's a formaldehyde protein polymer.

17 Q. Did I say hydrogen?

18 A. Yes. And it cross linked. If you think of
19 the legs of a ladder as being a long chain polymer,
20 cross linking means you would tie them together so you
21 make a real rigid material. If you had a link this
22 way, a link this way, a link this way, you tied them
23 together by cross linking them, you would produce a
24 very rigid molecule. And that's precisely what that
25 casing is around that polymer, very rigid, brittle,

1 hard. Almost impossible to remove.

2 Q. And what did Dr. Jordi, based on his report,
3 how did he go about trying to remove this new polymer
4 that was formed with the reaction between the protein
5 and the formaldehyde?

6 A. Dr. Jordi didn't look at the fiber itself.
7 He dried the material that he received, which is the
8 flesh that had been in formaldehyde. In reading his
9 documents, he used the tweezers to pull off as much
10 flesh as he could. What was left was dried and he
11 rolled the fiber on a hard surface and material flaked
12 off of it. And he analyzed the flakes. He never
13 analyzed the fiber itself. By FTIR. He did analyze it
14 by molecular weight, but he never obtained an FTIR
15 which would allow you to see the carbonyl group, that
16 we showed a moment ago and whether or not it's
17 oxidized.

18 Q. Okay. Now, when the PROLENE is in the body
19 is it encased in -- does it have some kind of soft bio
20 film on it?

21 A. It has a bio film that is not yet cross
22 linked. The proteinous material from the body that's
23 encasing the fiber, but it's not cross linked until
24 it's taken out and dropped in formaldehyde.

25 Q. Is it then kind of wet and oozy, or something

1 that's covering the mesh fibers?

2 A. Well, it would be fleshy like.

3 Q. But once you put it into the formalin and you
4 fix it, how does it become?

5 A. Hard and brittle.

6 Q. All right. Let's look at -- well, let me ask
7 you this.

8 What different types of tests then did you do
9 on the pristine sample?

10 A. I looked at those samples under electron
11 microscope and light microscope to be able to show you
12 what a pristine sample that has not been exposed to the
13 body would look like. A sample in its pristine form
14 would look like.

15 Q. Jamey, can you show, 13, if you would,
16 please.

17 I think the Jury ought to see what you had to
18 work with.

19 A. Okay.

20 Q. On the left, this is -- what is this?

21 A. That's the exemplar. That was a piece of
22 pristine polypropylene that was -- was carried along in
23 the cleaning process. And we cut a piece off to do the
24 microscopy work on it.

25 Q. All right. On the right is the total amount

1 of the mesh that you had to work with?

2 A. Yes, sir.

3 Q. So you didn't have a whole lot, did you?

4 A. No, sir, certainly didn't.

5 Q. Did you then try to determine a base line?

6 Something to compare the mesh, the explanted mesh
7 against?

8 A. Yes, sir.

9 Q. And is that why you did the testing of either
10 the pristine mesh or the exemplar mesh or both?

11 A. Yes, sir.

12 Q. Okay.

13 A. We used primarily the exemplar mesh because
14 it had been through the cleaning process just like the
15 explanted material had.

16 Q. Let's talk then about the types of tests that
17 you ran. First of all, what is an SEM, Dr. Thames?

18 A. SEM stands for Scanning Electron Microscope,
19 microscopy.

20 Q. And what does it do?

21 A. It will show you a very high magnification
22 and in great detail. It will give you a picture called
23 a photomicrograph.

24 Q. Let's look at some of the photomicrographs so
25 we can let the Jury see what you were seeing.

1 First of all, let's see, Jamey, a picture of
2 the pristine TVT mesh.

3 A. Correct.

4 Q. This was the one just taken out of the box
5 that had not been cleaned?

6 A. Correct.

7 Q. Okay. Go to the next slide.

8 A. That's at a magnification of 60 times.

9 Q. Okay. Then you looked at the exemplar?

10 A. Yes, sir.

11 Q. That which you would put through the same
12 cleaning process?

13 A. Yes, sir.

14 Q. This is magnified so you can see it a little
15 better, but it's at 203 times, right?

16 A. Yes, sir.

17 Q. All right. Then let's look at the Batiste
18 explant under SEM magnification?

19 A. Okay. That's at 308 times magnification.

20 Q. All right. Obviously it looks different than
21 what we've seen before?

22 A. Yes, sir.

23 Q. Why is this different? Explain to the Jury
24 what the difference is?

25 A. The difference is the fact that this material

1 you see here is the residual protein formaldehyde
2 polymer that formed around this fiber when it was
3 placed into formaldehyde.

4 You can see the striation lines of the
5 polypropylene that came from the dye. You can see
6 those very clearly.

7 There is another observation here that is
8 very practical, and I know you'll appreciate, is notice
9 the difference in the distance between the cracks here
10 and here. You'll notice the cracks here, the distance
11 is much smaller than they are here.

12 And if you'll look at my arm here a moment,
13 and assume my arm is the polypropylene fiber. It's
14 totally encased, if I bend it this way I'm compressing
15 the casing here, and I'm pulling the casing here.

16 So where there is a short distance between
17 that's the compression, and where there is around the
18 edge that's tensile, that means it's pulling apart. So
19 that's why there is a difference in the actual width
20 dimension between the two cracks.

21 So here is your polypropylene, and here is
22 your proteinous material which we were not completely
23 able to get rid of.

24 Q. Now, Dr. Jordi, when he was here, said that
25 this material; not this material, he did say that this

1 was the fiber, but he said this also was part of the
2 polypropylene, and it showed that it had cracked and
3 degraded.

4 Now, do you agree that that's what that is,
5 sir?

6 A. I do not.

7 Q. And first of all, let's talk about why you
8 didn't?

9 A. Okay.

10 Q. Did you do a measurement of the diameter of
11 each of the fibers?

12 A. I did.

13 Q. And did you do an analysis of the diameter of
14 the exemplar?

15 A. I did.

16 Q. And did you do an analysis of the diameter of
17 the fibers from the explant?

18 A. Yes, sir.

19 Q. Next slide, Jamey.

20 And are these the results of your measuring
21 the diameter of these fibers?

22 A. Yes, it is.

23 Q. Now, if the cracked portion were
24 polypropylene, that would mean some of it cracked off
25 that would make the diameter smaller, wouldn't it?

1 A. Absolutely.

2 Q. But when you did your measurements, you found
3 that when you measured the explant versus the exemplar,
4 that the diameter actually became larger?

5 A. Yes, sir.

6 Q. So does that mean instead of just being
7 polypropylene, you now have a coating over those
8 polypropylene fibers?

9 A. That's precisely what it means, sir.

10 Q. It's not going to grow any other way, is it?

11 A. No, sir.

12 Q. So is that one of the reasons why that you
13 feel that what was cracked off was not polypropylene
14 from the fiber, but rather was this formaldehyde
15 protein cross linked polymer? This stuff that
16 encapsulated the fibers?

17 A. Yes, sir.

18 Q. Dr. Jordi indicated that there was --
19 actually, he called it two separator fibers. He said
20 there was an inner fiber and an outer skin, and it was
21 the outer skin of the polypropylene that actually
22 cracked.

23 Did you, at my request, Dr. Thames, do a
24 cross-section of the fiber that was taken from
25 Ms. Batiste?

1 A. I did.

2 Q. And did you do did a cross-section of the
3 pristine fibers?

4 A. Yes, sir.

5 Q. And if there were a skin around the pristine,
6 then you would say that Dr. Jordi was correct, that
7 there were are, in fact, two separate -- there was a
8 core and a skin.

9 Did you find when you looked at the
10 cross-section of the pristine whether there was, in
11 fact, a core and a skin?

12 A. There was no core and a skin.

13 Q. Is this -- so that we can have some
14 understanding, it talks about an epoxy embedding resin.
15 What does that mean? Why did you do this, and how did
16 this occur?

17 A. If you can envision a fiber, a thread
18 sticking up like so, we're going to cut it right here,
19 that's a cross-section. You have to embed it in
20 something that's hard that would hold it in place.

21 And so we use an epoxy resin. You can buy
22 them at Lowe's or any other place, clear, and they will
23 set up very, very hard like glass. After it has
24 hardened, then you take a polishing machine, polish the
25 surface down so that it's smooth.

1 Then after you've done that, then you run
2 your analysis. You do your light microscopy, and this
3 is at 202 magnification. It's very obvious you can see
4 there is no skin core here. All one material, no
5 score, no skin on the outside. If there was, we would
6 see a demarcation between the two. There would be some
7 indication that there was a skin on the outside, kind
8 of like a piece of sausage. A link sausage.

9 Q. All right. Let's go to the next kind of
10 examination you did then, the FTIR?

11 A. All right, sir.

12 Q. What is the FTIR.

13 A. The FTIR, as I said, is a Fourier Transform
14 Infrared spectroscopy. I can't even get the word out.
15 And we use the attenuated total reflectants as the
16 method to use.

17 Now, what you do to get that sample is you
18 eradicate the sample that you're looking at with the
19 entire spectrum of energy. And the computer within the
20 machine will take that information that comes back and
21 at various places on that chain there is
22 characteristics about the polymer that you're looking
23 at that will absorb energy at various places along the
24 chain.

25 For instance, energy will be absorbed if a

1 molecule kind of wags a little bit, if the methyl group
2 moves, the energy will be absorbed.

3 If there's a carbonyl group like the C double
4 bond O that we said had to be present if it was
5 oxidized, that's a very strong peak and you'll see it
6 very evident in there.

7 So that's the fingerprint region, that's the
8 fingerprint of polypropylene. Every individual
9 molecule has a unique infrared spectra.

10 Q. Did you then -- is there a place that you can
11 go to find out this fingerprint for polypropylene?

12 A. Yes, sir. You can go to the library, just
13 like we go to the library, check out a book. We go to
14 the library of spectra that's been put together by
15 companies, and you can select for isotactic
16 polypropylene, that is the -- the spectra that you
17 would expect to see if you're looking at polypropylene
18 unadulterated, unoxidized pristine.

19 Q. You've also indicated that in your opinion
20 adhered to the fibers, the PROLENE, were these -- this
21 new cross linked polymer. That which -- would be
22 protein, correct?

23 A. Yes, sir.

24 Q. And did you go to the library to get a
25 spectra graph?

1 A. Yes, sir, I did.

2 Q. For protein?

3 A. Yes, sir.

4 Q. Let's show that. So you got both of those?

5 A. Correct.

6 Q. And then you would do your examination and
7 you would run it through the FTIR to see what? What
8 are you looking for?

9 A. I'm looking for any indication that
10 polypropylene was oxidized or that its structure was
11 changed by virtue of being implanted in Ms. Batiste.

12 Q. You just indicated a minute ago that if you
13 had oxidation, you would have an intense carbonyl peak,
14 I believe you said?

15 A. Yes, sir.

16 Q. When you got Dr. Jordi's report did you find
17 cited in that report an article that gave you an
18 example of the peak you would find if the polypropylene
19 had been oxidized?

20 A. Yes, sir.

21 Q. Let's look at that, if you would, please?

22 A. Yes, sir.

23 Q. And where is the carbonyl peak that's there
24 on that diagram? This is from the Wood article that
25 Dr. Jordi cited, is that correct?

1 A. Yes, sir. That peak is right here, sir.

That's 1740 reciprocal centimeters, 1740, there you go.

3 | Thank you.

4 Q. This is Defendant's Exhibit --

A. This peak right here.

6 Q. Where it says over -- and this is actually
7 from the article itself, where it says carbonyl peak,
8 1740?

9 A. Yes, sir.

10 MR. NOTEWARE: This is Defendant's
11 Exhibit 10792, counsel.

12 A. Please note, sir, that it says explanted
13 polypropylene, and from this amount it shows that that
14 is the peak that's present when polypropylene has
15 oxidized. And the blue peak is polypropylene that has
16 not oxidized.

17 Q. Okay. So we have then -- it's clear, and
18 that the whole point of the article is that in this
19 case the polypropylene that was used there, which was
20 not PROLENE had oxidized, correct?

21 A. Yes, sir.

22 Q. Now, what is it that is unique about carbonyl
23 bonds?

24 A. Carbonyl bonds have the carbon atom attached
25 to an oxygen atom and their polarity is much different

1 and as a result of that there's a shift of electrons
2 moving toward the oxygen. And that, in effect, makes
3 it very difficult to stretch that bond, and when it is
4 it gives an intense peak.

5 So that particular functional group has an
6 intense absorption frequency, and I'll just say that it
7 has a high extinction coefficient, and let it go at
8 that. That's why it's high.

9 Q. Did you run an FTIR analysis on the explanted
10 fibers themselves?

11 A. I did, sir.

12 Q. And let's look at the next.

13 Is this the result of your FTIR analysis?

14 A. Yes, sir, it is.

15 Q. Tell the Jury what you see there, more
16 importantly what you don't see there?

17 A. What I don't see is important, too. This
18 peak right here, this peak right here, all of these
19 peaks as a matter of fact, and all of these peaks right
20 here are indicative of isotactic polypropylene in its
21 unaltered state. There is no 1740 -- may I move around
22 there to show?

23 Q. Yes. Just come down here, though, I think,
24 Dr. Thames.

25 A. Yes, sir.

1 You would expect to see that 1700 right
2 there. We would expect to see an intense peak right
3 here, if that was oxidized polypropylene, just like the
4 sample before we showed, this sample does not have that
5 peak, it means it doesn't have a C double bond O, which
6 means it's not oxidized.

7 Q. All right. Dr. Jordi did an FTIR, and it's
8 configured differently, because he didn't use the same
9 kind of FTIR machine that you used, did he?

10 A. No, sir.

11 Q. What kind did he use and how is it different
12 from the one that you all used?

13 A. Well, we used attenuated total reflectance,
14 meaning the light is shown on the sample and bounced
15 back to the detector, shown again, bounces back. It's
16 attenuated total reflectance.

17 He used the --

18 Q. Actually, Evens used it, but at his request.

19 A. Well, I used the attenuated total
20 reflectance.

21 Q. Yeah.

22 A. What he used was transmission spectroscope,
23 which required the light to go all of the way through
24 the sample before it got to the detector. And when you
25 do that, you have to be very careful about the

1 thickness of the sample that you use, because if it's
2 too thick, you don't get enough light to go through and
3 your spectra are not typically very good.

4 Q. All right. He did an FTIR analysis using
5 this other method, and let's look at his results. If
6 there had been oxidation, what would you have found,
7 what would you have seen?

8 A. You would have seen a strong band right here
9 going like this at 1740. See, this is 1661. This is
10 1760, that he has marked himself. The machine didn't
11 mark this. So it would have been, right here would
12 have been that strong band. That's what you would have
13 to have or have to be seeing to confirm that you had
14 oxidized polypropylene.

15 Q. There are numbers on there, and maybe we
16 ought to explain to the Jury how the numbers get there.
17 Who puts them there, what puts them there, how does
18 that happen?

19 A. You can ask your machine, the operator can
20 tell your machine to mark the significant peaks, the
21 wave length of absorption of the significant peaks.
22 And that's what the instrument has done, it's marked
23 these significant peaks for this particular sample.

24 It did not mark this peak or this shoulder
25 right here. As you can see, that's a different font,

1 and I think Dr. Jordi has agreed that he put that
2 marking himself in there with an arrow. The machine
3 didn't mark it because the machine said it's not
4 significant.

5 Q. What does that tell you, then, whether or not
6 the mesh that had been explanted from Ms. Batiste
7 oxidized or not?

8 A. It did not oxidize.

9 Q. And can you say that with reasonable
10 scientific certainty?

11 A. Yes, sir.

12 Q. Just a couple follow-up questions,
13 Dr. Thames, and we're done.

14 A. All right, sir.

15 Q. You've done pretty well.

16 A. Thank you.

17 Q. First of all, do you have an opinion based on
18 a reasonable degree of scientific certainty as to
19 whether there was any evidence of degradation on the
20 mesh that was taken from Ms. Batiste?

21 A. I do have an opinion.

22 Q. And what is that opinion?

23 A. There was no evidence of any kind that would
24 suggest that there was degradation of Ms. Batiste's
25 device that was implanted in her and explanted.

Q. Do you have an opinion, Dr. Thames, based on a reasonable degree of medical certainty as to whether or not there was any evidence of oxidation on the material that was explanted from Ms. Batiste?

A. Yes, I do.

Q. And what is that opinion?

A. My opinion is there was no oxidation, as I pointed out here in Court.

Q. Based on the foregoing, do you have an opinion, Dr. Thames, as to whether or not the TVT mesh performed as it was intended to perform from a chemical perspective?

A. I do.

Q. And what is that opinion?

A. It did perform as it was intended to do from a chemical perspective.

MR. NOTEWARE: I have no other questions.

THE COURT: All right, ladies and gentlemen, let's take a ten minute break and be back in ten minutes.

(Recess)

THE COURT: Be seated, please.

CROSS-EXAMINATION

BY MR. CARTMELL:

1 Q. Good afternoon, Dr. Thames.

2 A. Good afternoon.

3 Q. This won't take too long. It's Friday
4 afternoon, everybody wants to go home.

5 I want to ask you some follow-up questions.

6 A. Sure.

7 Q. You testified, I believe, that you had never
8 tested a polypropylene prior to getting involved in
9 this litigation, is that right?

10 A. That's correct, tested, yes, sir.

11 Q. So you had never looked at polypropylene or
12 tested polypropylene like the PROLENE mesh to see if it
13 had degraded prior to getting involved in this
14 litigation, is that fair?

15 A. That's correct.

16 Q. Now, prior to getting involved in this case,
17 is it true that you have served as an expert witness on
18 behalf of Mr. Gage's firm Butler Snow, several times
19 over the last ten years?

20 A. Yes, sir.

21 Q. And I think you testified in your deposition
22 that you've given -- you've served as an expert witness
23 and given approximately 50 depositions?

24 A. Yes, sir.

25 Q. And what do you charge for your time?

1 A. \$375 an hour.

2 Q. And how much have you charged in this
3 lawsuit?

4 A. About 52 hours.

5 Q. And then in another case, I think you were
6 paid about \$120,000?

7 MR. NOTEWARE: Excuse me, Your Honor,
8 I'm going to object. That goes beyond proper
9 examination of this witness.

10 THE COURT: Sustained.

11 Q. You've worked on other cases during your
12 career with Butler Snow? Mr. Gage's law firm?

13 A. Not other than the ones you've already
14 mentioned, sir.

15 Q. No, I understand, but in another lawsuit
16 you've charged and were paid about \$120,000?

17 A. That's approximately right, yes, sir.

18 Q. How much do you think you've been paid by
19 Mr. Gage's law firm over the last ten years?

20 A. I have no idea, sir.

21 Q. When you testified, I think you said in your
22 deposition, 99 percent of the time that you have
23 testified, it's been on behalf of a large corporation,
24 is that right?

25 A. I don't think I said large corporation s I

1 said Defendants. And that's because I haven't been
2 asked by Plaintiffs, I believe is the way I phrased it.

3 Q. In product defect cases it's on behalf of the
4 Defendants who are corporations, correct?

5 A. That's correct.

6 Q. Let's take a look at Ms. Batiste's photos
7 that Dr. Jordi took.

8 You've seen Dr. Jordi's report, obviously?

9 A. I have.

10 Q. And your testimony is that the surface area
11 cracks seen in the SEM pictures that were taken from
12 Ms. Batiste, your testimony is that is a formaldehyde
13 protein polymer covering, sort of, is that right?

14 A. That's correct.

15 Q. You've also seen there's been other pictures
16 from other explanted mesh from I believe 23 other women
17 that were evaluated, have you seen those?

18 A. No.

19 Q. You never saw those?

20 A. No, sir.

21 Q. These are some of the photos that were
22 reviewed by Dr. Jordi and provided in a report by him.
23 It sounds like you haven't seen these. But is it your
24 testimony that these would be a formaldehyde protein
25 polymer covering over the mesh?

1 A. Based on what I see, that would certainly be
2 my best estimate of that, yes, sir. Not only what I
3 see, but what I know, I guess, is a better way to put
4 it.

5 Q. When you did your testing, I think you
6 mentioned some things about your process, and you may
7 have mentioned this, but I think what you did was you
8 soaked the sample from Ms. Batiste in different
9 chemicals for about 180 hours, is that right?

10 A. I didn't add them up, but for a long time and
11 that was necessary to attempt to get that armor of
12 proteins and formaldehyde layer off of it.

13 Q. Have you ever seen any protocol or any
14 publication that says that in order to test for
15 degradation of polypropylene mesh that comes out of a
16 woman, that it should be soaked in chemicals for 180
17 hours? Have you ever seen anything like that?

18 A. Well, I don't really quite know how to
19 respond to your question because I don't know that it
20 has anything to do with what I've just talked about or
21 this case. Because what I've stated here is that this
22 protein and formaldehyde has formed a casing around the
23 fiber and that I have seen no standardized methods for
24 cleaning samples. So I have to devise a method that
25 is, in my view as a scientist, polymer scientist,

1 technique and knowing what's happened to the protein
2 how it's polymerized, the best way to get it off. And
3 it's a very tenacious material and it just doesn't come
4 off very readily, sir.

5 Q. You've seen publications in the past, there
6 are scientists, that lot of them that have published on
7 whether or not polypropylene can degrade, right?

8 A. There are. And unfortunately, the vast
9 majority of those individuals are not aware of the
10 reaction, obviously are not, because they've used
11 sodium hypochlorite in a few hours said the samples are
12 clean and they're not. There's no way that you can
13 clean that tissue and that protein formaldehyde polymer
14 from polypropylene, in the small amount of time and the
15 chemicals that they used to remove it. It just will
16 not happen.

17 Q. You believe that the published articles, and
18 the authors of those published articles going back over
19 a number of years, you believe all of those scientists
20 that have, many of them for their -- good part of their
21 career, including Dr. Jordi, have tested polypropylene
22 products, you believe that they just missed it, and
23 they were wrong about this whole theory you have?

24 A. It's not a theory, first of all, it's fact.
25 It's published. It was published in 1949. I think it

1 was put there for the Jury to understand that
2 formaldehyde does react with proteins to form a
3 composite polymer. Well known.

4 It's in the surgery literature. I think you
5 used that -- asked me to blanket statement to include
6 everybody that's ever published. No, that's not the
7 case. There are articles I believe where people have
8 misjudged what the effects of that particular chemical
9 reaction we're talking about is on the cleaning of the
10 implant. I believe they think they cleaned it, but
11 they did not. And I don't believe they're polymer
12 scientists.

13 Q. Was that 1949 article, was that a test of a
14 sample of polypropylene that was removed from a body?

15 A. No, sir. The 1949 article was an article
16 that describe the chemical reaction between protein and
17 formaldehyde and described the fact that it would make
18 this huge polymeric species. And this is in numerous
19 other pieces of literature that I've read where they
20 talk about fixing the fiber, or fixing the flesh or do
21 histological studies. It's well known in the community
22 that formaldehyde fixes the flesh by forming a polymer,
23 and this is the polymer that I described to you. It's
24 well known.

25 Q. And do any of those articles you're talking

1 about deal with -- talk about formaldehyde and
2 polypropylene mesh or sutures coming out of bodies, and
3 that that forms -- are any of them dealing specifically
4 with those products?

5 A. Well, the chemical reaction --

6 Q. Well, let me ask you this. I don't mean to
7 interrupt you, but can you answer me if any of those
8 studies or documents that you're talking about, do any
9 of those deal with formaldehyde protein reactions on a
10 polypropylene suture or mesh that came out of a
11 person's body? Do you know?

12 A. May I tell you what I think you're asking me?

13 Q. I'm asking if any of those studies,
14 literature that you read deal with those products, mesh
15 product, suture polypropylene product that has come out
16 of a woman's or a human's body. Do any of them deal
17 with that?

18 A. I don't think I read where they specifically
19 talk about encasing polypropylene, but I've talked
20 about the chemistry will encase whatever it surrounds.

21 Q. In order to form -- well, let me ask you.
22 One of the things you said you did, you soaked it for
23 180 hours. Have you ever seen anything in a paper that
24 says soak it for more than two hours or three hours?

25 A. Yes, sir.

1 Q. What's the longest you've seen?

2 A. Well, I think I've seen some papers for up to
3 96 hours, over a hundred hours.

4 Q. In polypropylene?

5 A. Wait a minute, maybe we're not talking the
6 same thing. Would you reask your question, please?

7 Q. Yeah. I was just saying in a polypropylene
8 product, suture or mesh, have you ever seen any
9 literature the that describes the process of soaking it
10 for 180 hours in chemicals before testing for
11 degradation?

12 A. To clean it?

13 Q. Yes, sir?

14 A. Yes, sir, I have.

15 Q. For 180 hours?

16 A. I don't know 180, I've seen over a hundred.

17 Q. And when you cleaned it afterwards, there was
18 pieces that came off that you actually, I think,
19 scraped off, is that right?

20 A. No, sir.

21 Q. Did anybody?

22 A. No, sir.

23 Q. Were there any pieces that came off the mesh?

24 A. I didn't collect the pieces, sir. I was
25 interested in looking at the fiber itself.

1 Q. Did Dr. Ong collect the pieces?

2 A. No, sir, not to my knowledge.

3 Q. Does Dr. Ong work for Exponent?

4 A. Yes, he does.

5 Q. And he did the FTIR testing for you?

6 A. No, sir, he did not. I did the testing.

7 Q. What testing did he do?

8 A. He did the cleaning of the explant, sir.

9 Q. And does he work for a company called
10 Exponent?

11 A. Yes, sir.

12 Q. You understand that Exponent has been paid
13 millions of dollars by the mesh companies?

14 MR. NOTEWARE: Your Honor, I'm going to
15 object. There is no foundation, no evidence for this.

16 THE COURT: Overruled.

17 Q. Do you know?

18 A. I don't have any idea, sir.

19 MR. CARTMELL: Do we have Dr. Ong's
20 deposition testimony at 12613, page 74.

21 Q. Have you ever read his deposition?

22 A. Yes, I have but it's been awhile.

23 Q. It says.

24 QUESTION: You preserved the material
25 that was removed from the outer layer of those meshes

1 so they could be tested, right?

2 ANSWER: And I have preserved them, I
3 have preserved the solutions.

4 Do you see that?

5 A. I do.

6 Q. If you go down. It says.

7 QUESTION: Hold on, you preserved the
8 solution in this case?

9 ANSWER: Yes, I did.

10 QUESTION: Where are the solutions
11 located?

12 ANSWER: They're sitting in our lab.

13 Have you ever seen those?

14 A. I don't remember it. No, I have not.

15 Q. Then if you go down?

16 QUESTION: Why haven't you tested the
17 solutions for the presence of polypropylene?

18 ANSWER: That was not within my area of
19 expertise.

20 Do you ever see that?

21 A. Yes, sir.

22 Q. Now, have any of those solutions that were
23 removed from the explant from Ms. Batiste, have those
24 ever been tested by anybody?

25 A. I don't know. I haven't tested them. I

1 haven't looked at them.

2 Q. I think he testified that they're in his
3 office in a tube or something like that. If you wanted
4 to, could you test those, or could Dr. Ong at Exponent
5 test those?

6 A. I don't know what I would test them for, sir.

7 Q. Could you test them for the presence of
8 polypropylene?

9 A. I gather so, yes, sir.

10 Q. And if a material that came off was
11 polypropylene that had flaked off the mesh, what would
12 that tell you, anything?

13 A. I would not be surprised that there might be
14 some polypropylene in those samples, because as I've
15 testified to before, that when those flakes that are
16 adhered tenaciously to polypropylene break off, small
17 amount of polypropylene comes with it. It's just like
18 a piece of duct tape that you put on a wall and then
19 stretch it off, you're going to take some of the paint
20 with you. So I'm not at all surprised to that. I have
21 testified to that before.

22 Q. So you got, when you cleaned this surface
23 after soaking it for 180 hours, you got down far enough
24 that you wouldn't be surprised that you were into the
25 polypropylene, and some of that flaked off, is that

1 right?

2 A. No, sir, that's not what I'm saying.

3 Q. How would some of the polypropylene be in the
4 solutions, if you hadn't gotten the outer -- outer
5 layer of it off?

6 A. I'm making the likelihood or the fact that
7 probably some of it did fall off. And if it did, then
8 it would be in the solution.

9 Q. And they could be tested, and we could figure
10 that out, correct?

11 A. Well, perhaps. I would have to test it first
12 to give you a definitive answer.

13 Q. Okay.

14 Now, did you read internal documents from
15 Ethicon? Were those provided to you in order to form
16 your opinions in this case?

17 A. I'm not sure I understand your question, sir.
18 I form my own opinions.

19 Q. Well, I just mean, did Ethicon through their
20 lawyers, give you Ethicon internal documents? Actually
21 we know they did, that was a dumb question, because you
22 got the seven-year are dog study.

23 A. Oh, yes, sir. Yes, sir.

24 Q. And did you read the five-year results of the
25 dog study?

1 A. I remember reading it, yes, sir.

2 Q. Okay. Exhibit 4012, we've looked at this
3 before with Dr. Jordi. I'll provide you a copy of
4 that.

5 A. Okay.

6 Q. This was the five-year results of the dog
7 study. Just so it's clear.

8 MR. CARTMELL: This is seven-year.

9 Q. I apologize. This the is seven-year, not
10 five-year?

11 A. Yes, sir.

12 Q. You've talked about this.

13 1992, and these were pieces of suture that
14 were put in dog's hearts, right?

15 A. Yes, sir.

Q. This was not a mesh study?

A. That's correct.

18 Q. And if you go down to the first paragraph, or
19 excuse me, the second page it says IR Spectra obtained
20 for cracks, PROLENE specimens showed possible evidence
21 of slight oxidation, do you see that?

22 A. I do.

23 Q. So in the 1992 dog study they showed
24 slight -- they found slight oxidation, and they found
25 cracks, correct?

1 A. Well, first of all, that's really not what
2 this says. It says possible evidence of slight
3 oxidation. And it goes on to say, A broadened weak
4 absorption at about 1650 reciprocal centimeters.

5 First of all, we've seen already that we
6 don't have a broad absorption oxidation. When you have
7 carbonyl peaks from oxidation, you get a very sharp
8 one. That was shown in the Wood article.

9 Secondarily, the 1650 reciprocal centimeters
10 comes from not protein, sir, not from polypropylene
11 oxidation.

12 Q. So you think these Ethicon internal
13 scientists, who were looking at the dog study that they
14 did, when they say that they showed possible evidence
15 of slight oxidation, your belief is they didn't see any
16 oxidation, correct?

17 A. I believe that they're misinterpreting the
18 fact that the 1650 broad peak, that's protein.

19 Q. Okay. Do you disagree or do you agree with
20 them that they saw cracked PROLENE specimens?

21 A. Well, I have to look at the totality of the
22 data that's been collected here in order to give you a
23 good answer for that.

24 And the totality of the data from
25 Mr. Berkeley, and his colleagues is the fact that there

1 bass no change in molecular weight of the polypropylene
2 after seven-year dog study.

3 There was improvements in the physical
4 properties after seven years. The dog study, as we
5 pointed out in our charts.

6 There is no indication, therefore, that there
7 was a crack that would adversely affect or deteriorate
8 the polypropylene after seven years in the dog study.

9 The facts are just not there.

10 Q. Jamey, would you mind pulling this up.

11 So what you're saying is you think they
12 probably just misinterpreted what they found?

13 A. I think so.

14 Q. They were wrong, in other words?

15 A. I don't think they looked at all of the
16 factors and put it together, sir.

17 Q. Okay. This is the slide you showed from the
18 dog study, correct?

19 A. Yes, sir.

20 Q. Does this slide deal with dog 1995 at the
21 top?

22 A. That's what it says, sir, yes, sir.

23 Q. Right. Admittedly there were some dogs that
24 didn't show degradation in this study, correct?

25 A. Well --

1 Q. First of all, is that true?

2 A. There were dogs that had different results.

3 There were dogs where they didn't see any cracks.

4 Q. Right. What you've shown here at the top is
5 a dog where they say, the scientists from Ethicon
6 in 1992, that they say there was no degradation.

7 That's what had you've shown at the top, correct?

8 A. That's what they say is no degradation.

9 Q. Right. And the scientists concluded that
10 there were other dogs, or PROLENE that came out of
11 other dogs, where they did find degradation, correct?

12 A. Well, that's what they said, but that's where
13 the molecular weight data comes in and didn't all mesh
14 out to show the total picture.

15 Q. So if you go to the conclusions of this,
16 let's go back to 4102, of this seven-year dog study.

17 A. Yes, sir. Do you want me to turn to that,
18 sir?

19 Q. Yes, please. Or you can look at it.

20 It states, Degradation in PROLENE is still
21 increasing, and PVDF, even though a few cracks were
22 found, is still by far the most surface resistant
23 in-house made suture in terms of cracking.

24 Do you see that?

25 A. I see that.

1 Q. Again, you showed previous documents dated
2 previous dates, and this was -- and I understand you
3 don't agree with it, this is Ethicon's 1992 conclusion
4 of whether or not there was degradation they saw,
5 correct?

6 A. Ethicon employees, yes, sir.

7 Q. Have you ever seen the 1987 PROLENE test from
8 human sutures that were taken out of humans where they
9 tested for degradation at Ethicon?

10 A. I don't believe so, no, sir.

11 Q. 4128. This was actually a document that was
12 produced to us by Ethicon, actually just real recently.
13 I think maybe after -- after your deposition, actually.
14 A few days before trial. And you've never been
15 provided this, it sounds like?

16 A. I have not seen this document.

17 Q. If you go down it states, IR microscopy of
18 explanted PROLENE received from Professor R -- is it
19 Guidoin?

20 A. Yes, I would say so.

21 Q. Professor Guidoin ends up being later on
22 publications relating to degradation, correct?

23 A. I've seen a lab sheet from Professor Guidoin,
24 yes, sir.

25 Q. Below that it states, samples of PROLENE

1 suture carefully removed from human vascular graft
2 explants received in Professor R. Guidoin were examined
3 by IR microscope, quote, as is?

4 A. Yes, sir.

5 Q. A PROLENE suture control was examined for
6 comparison, and the samples are described as follows.
7 Do you see that?

8 A. I see that.

9 Q. Below it gives examples of what they found.
10 And they give the duration that these sutures, again,
11 this is not mesh, this is smaller pieces of suture.
12 They show what they found. At two years, they found no
13 cracking. And at eight years, they found severe
14 cracking on several of the sutures that they examined,
15 is that correct?

16 A. That's what it says, sir.

17 Q. And then if you go down it says, Using a
18 needle -- in the bottom paragraph.

19 It says, Using a needle, the cracked surfaces
20 were easily wiped off and deposited on a KBr window.
21 The surface scrapings had the handling and consistency
22 of a waxy snow. The sample was not conducive to IR
23 microscopy in this form, however. Similar treatment
24 with needles on sterile packaged PROLENE and the two
25 year sample generated no scrapings.

1 Do you see that?

2 A. Yes, and I'm not surprised.

3 Q. At this time they actually scraped off some
4 material from these, right?

5 A. Yes, I'm not surprised.

6 Q. Then under the conclusion section on the next
7 page I want to ask you a few questions about this.

8 A. Okay.

9 Q. 1987, the first paragraph says, The amount of
10 DLTDP is reduced in the sutures. No DLTDP is observed
11 in the surface scraped cracked regions.

12 A. I'm not surprised.

13 Q. And you talked about, I think, I can't
14 pronounce the word either, but DLTDP, that's one of the
15 antioxidants?

16 A. That's one of the two.

17 Q. Is that the one that is for longer term
18 protection?

19 A. They're both long-term protection. They work
20 synergistically with each other. Together they're
21 better than either one alone.

22 Q. We talked about with Dr. Jordi sort of the
23 bodyguard that will protect it inside the body,
24 correct?

25 A. Would you please restate that, sir.

1 Q. Dr. Jordi talked about how you could think
2 about it in layperson's terms, sort of as the Santonox
3 and this, as sort of a bodyguard that would protect the
4 PROLENE or the polypropylene inside the body from
5 degradation?

6 A. I prefer to say it's there to give it
7 longevity.

8 Q. Okay, longevity. What they found, they found
9 that didn't exist on the scrapings, correct?

10 A. On the scrapings, and I'm not surprised.

11 Q. And then it says, No protein is observed in
12 any spectra of the explanted sutures. Do you see that?

13 A. I do.

14 Q. So they didn't find protein on the sutures on
15 the ones even that were explanted after eight years,
16 right?

17 A. That's what they say.

18 Q. You disagree with that?

19 A. Well, sir, you're asking me a question about
20 something I'm just now looking at here. There's a
21 number of spectra. If you don't mind, I'll take a
22 second look at them.

23 Q. I was going to ask you about the third
24 conclusion, too.

25 A. Okay, sir.

1 Q. The third opinion states, The surface scraped
2 material from the cracked regions of A30035 has a
3 melting range of indicative of degraded polypropylene.
4 Do you see that?

5 A. Yes, sir.

6 Q. IR spectra of this scraped material is
7 clearly polypropylene?

8 A. I see what it says, yes, sir.

9 Q. Just like what Dr. Jordi did in 2013, I
10 believe, the scraped material was taken off the
11 PROLENE, it was tested, and it tested to be
12 polypropylene. Correct?

13 A. That's what he says, yes, sir.

14 Q. And they found in this 1987 test that Ethicon
15 did that when they looked at this material, it had a
16 melting range that told them there was degraded
17 polypropylene.

18 Do you disagree with that?

19 A. I see what it says, sir, but I believe I can
20 explain to you why there's a depressed melting point
21 that's not being mentioned here. I think I know why
22 that is.

23 Q. Let's, first of all, get clear. These
24 scientists, at least from Ethicon --

25 A. Yes, sir.

1 Q. -- I guess I know where you're going, but
2 they concluded that there was severe cracking and
3 degradation, correct?

4 A. What is said here was said. I'm not arguing
5 about what's written here.

6 Q. You would agree with me that based on your
7 review, you're a polymer scientist, these scientists at
8 Ethicon concluded that there was severe cracking and
9 degradation of the PROLENE, correct?

10 A. That's what they say.

11 Q. And I understand your testimony is you
12 disagree with them, is that right?

13 A. Well, I have a reason for it, it's not
14 just --

15 Q. I'm not disputing that. I'm sure you have
16 your reasons.

17 A. I think there are other factors that need to
18 be looked at before this was written up.

19 Q. Okay. I'm going to let you talk about that
20 with the attorney who hired you, so we can move on and
21 go.

22 A. Okay.

23 Q. Now, you also reviewed, in preparation for
24 your opinions the -- is it the Mary Celine article, is
25 that right?

1 A. Yes, sir.

2 Q. And that is an article Exhibit 4114, a 1998
3 article where --

4 A. May I have that, sir?

5 MR. CARTMELL: Yeah, let me get it.

6 Q. So this is Mary Celine. This is in the ASAIO
7 Journal in 1998, Mary Celine and several other
8 investigators?

9 A. Yes, sir.

10 Q. Do you know any of those authors?

11 A. No, I do not.

12 Q. Do you know whether or not they're polymer
13 scientists?

14 A. I do not.

15 Q. In this study in 1998, they actually looked
16 at PROLENE, the same material that's used in the mesh,
17 is that right?

18 A. Yes.

19 Q. And they compared it against PDF, did they
20 not?

21 A. That's correct.

22 Q. Actually, that's what the dog study did, they
23 compared PROLENE to the PDDF, is that right?

24 A. Yes, sir.

25 Q. If you go to page 2002?

1 A. You mean 202.

2 Q. Oh, yeah, I'm sorry, 202. I'm losing it, I'm
3 losing my brain.

4 It says -- in the right-hand column, sir, it
5 says, After one and two years of implantation the
6 surface of the retrieved and cleaned VF sutures did not
7 appear to be substantially modified. In contrast, the
8 polypropylene sutures explanted one and two years
9 postoperatively showed evidence of surface
10 deterioration, characterized by uniformly spaced
11 circumferential cracking and peeling and flaking of the
12 polymer material in the outer most surface layer.

13 Do you see that?

14 A. I do, and there's a reason for that.

15 Q. What's the reason?

16 A. The reason for that is these particular
17 explants were fixed in formaldehyde and other aldehydes
18 as well. So there was a reason for that material, the
19 formaldehyde protein layer to form around that explant,
20 and that's what in my opinion she is seeing. It did
21 not -- so we're looking at essentially the same kind of
22 chemistry that we've been talking about here today.

23 Q. So you also -- because they didn't mention
24 anything about that, right?

25 A. Yes, they did. She talked about how far they

1 fixed the fibers they used glutaraldehyde.

2 Q. I didn't mean that. You're right, they did
3 fix it in formaldehyde.

4 A. Right.

5 Q. But their conclusion in the study was that
6 polypropylene degrades in PROLENE, correct?

7 A. Well, I don't know that they used the word
8 degrade. Can you point me to that?

9 Q. I was just saying it showed surface
10 deterioration characterized by uniformly spaced
11 circumferential cracking and peeling and flaking of the
12 polymer?

13 A. Surface would be the protein formaldehyde
14 polymer, that's correct.

15 Q. Their conclusion was that it was
16 polypropylene, not what you say that it's a film that's
17 put over it as a result of formaldehyde, correct?

18 A. Would you restate your question, please?

19 Q. Sure. You disagree with these investigators
20 because what they had concluded was cracking -- the
21 peeling and cracking and flaking that they saw, they
22 concluded that that was polypropylene that was peeling
23 and flaking, right?

24 A. I believe they did, and I don't agree with
25 that.

1 Q. So you disagree with all of these
2 investigators as well?

3 A. I do.

4 Q. If you look at 203, in the right-hand column,
5 it states -- in the end of the first paragraph it
6 states, It has long been known that polypropylene is
7 susceptible to degradation by several different
8 initiation phenomenon including thermal, mechanical,
9 photochemical, radiation, biologic and chemical
10 mechanisms.

11 Do you see that?

12 A. I see it, yes, sir.

13 Q. Do you agree with that?

14 A. Just one second, please, sir.

15 I believe that that is possible under certain
16 conditions, which were not here in this piece that was
17 explanted.

18 Q. Would you agree with me that soaking the
19 explant in chemicals for 180 hours could cause the
20 explant to swell?

21 A. Depends on what it was soaked in, sir.

22 Q. In the chemicals in which you soaked it in,
23 would you agree with that?

24 A. I don't believe so because I've measured the
25 explants in the cleaning that we did, and it was

1 essentially the same as the pristine sample, so, no,
2 not in my case.

3 Q. Well, did you measure the explant before you
4 soaked it in the chemicals?

5 A. Yes, sir.

6 Q. You have a measurement before and after?

7 A. Yes, sir.

8 Q. And the pristine as well?

9 A. Yes, sir.

10 Q. I'm trying to cut out some stuff here.

11 A. Thank you.

12 Q. Your opinion in this case is that the protein
13 formaldehyde theory causing a cracking on the surface
14 of the mesh fiber is a novel opinion, correct?

15 A. No, sir. No, it is not. I pointed out to
16 you what's novel about this is that people haven't
17 noticed this 1948 reaction and noticed that it is
18 encapsulating and reacting with proteins. The fact
19 that it happens is not novel at all. It's 60 years
20 old. I just don't understand why people haven't
21 noticed it.

22 Q. Let's see page 358, lines 5 through 24.

23 QUESTION: All right. So your opinion,
24 some of your opinion are novel opinions?

25 ANSWER: Well, they have been and they

1 may well be they may not be.

2 QUESTION: Including your opinions that
3 the cracks observed on the explant material, both prior
4 to and after the 20 step process, is protein.

5 Then if you go to 359, 1 through 10.

6 A. It says, I don't know if it's novel or not.
7 I believe.

8 Q. Including your opinions that the cracks
9 observed on the explant material -- I read that -- both
10 prior to and after the 20 step process is protein.

11 ANSWER: I think I've testified that
12 it's protein formaldehyde encasement.

13 QUESTION: A novel idea?

14 ANSWER: I don't know if it's novel or
15 not, I haven't seen it before. And other people may
16 well know that, but -- what I've read in this
17 particular matter, I haven't seen expressed.

18 In fairness to you, right, you just haven't
19 seen anybody else that's ever had that opinion. They
20 may have had it, you've just never seen it.

21 They may have had it, you've just never seen
22 it.

23 A. And I'm really surprised.

24 Q. And you can't tell us whether your opinions
25 in this case are generally accepted in the scientific

1 community, correct?

2 A. Well, now, I wouldn't go that far. I believe
3 my opinions, what I've stated, would be accepted in the
4 scientific community.

5 Q. 358. Five through 24.

6 Your ideas aren't generally -- your opinions
7 regarding protein aren't generally accepted in the
8 scientific community, are they?

9 ANSWER: I don't know whether they are
10 or not.

11 A. I believe my point was, if I published this
12 article then I would have a means of knowing whether it
13 was accepted by the scientific community. I haven't
14 published the article, so how would I know if the
15 scientific community accepted it, but I believe if I
16 published it they would.

17 Q. My point is, as of today, there hasn't been
18 anything published on it, so we don't know?

19 A. There has been, sir.

20 Q. I'm just talking about your opinions related
21 to polypropylene mesh like you're giving in this case,
22 that when it's soaked in formaldehyde after it's
23 explanted from a woman's pelvis, and that that creates
24 the reaction. I understand there's a 1949 and some
25 other articles about the reaction, my opinion, what I'm

1 getting at, there is just no published literature to
2 support the opinions so far that you're giving other,
3 than that there's this reaction?

4 A. No, that's not true.

5 Q. Okay. What other --

6 A. There's published documents in the surgery
7 manuscript and procedures about fixation to tissue with
8 formaldehyde and it's available for doctors to read. I
9 read one last night. I don't remember the article,
10 it's there. It's in the surgery journals.

11 I mean, the histologists know it. They use
12 formaldehyde to fix their samples with.

13 Q. When you were under oath and you were asked
14 the question, you said, I don't know whether they are
15 or not, didn't you?

16 A. I think that's a little out of context, sir.
17 I don't believe I meant that like that.

18 Q. Now, in Ethicon's dog study that we've talked
19 about where the sutures came out, they did not use
20 formaldehyde in that study, correct?

21 A. That's correct, sir.

22 Q. And the scientists who were doing the study
23 concluded that there was cracking and degradation,
24 correct?

25 A. That's what he said.

1 Q. The 1987 study concluded that there was
2 degradation of polypropylene, correct?

3 A. Well, let me go to 1987 here, sir. Where are
4 you, sir?

5 Q. 1987, they looked at that and determined that
6 there was severe cracking and degradation, correct?

7 A. What line are you, on, sir? I must be
8 missing it.

9 Q. This is what we just looked at, sir. We
10 looked at the severe cracking on the first page.
11 Second page, we went through the conclusions that
12 talked about degradation, and you said you disagree.
13 Do you remember?

14 A. Well, I disagree with a lot of the -- well,
15 with some of the opinions that have been expressed
16 here, and the interpretation of the data.

17 Q. Okay. Let's go to the next slide. The 1992
18 Ethicon dog study, you also agree with the conclusion
19 of degradation there, correct?

20 A. 1992.

21 Q. That's the seven-year dog study?

22 A. Did you say agree?

23 Q. No, you disagree?

24 A. Yes, I do.

25 Q. You disagree with the 1998 Celine Mary,

1 article, correct?

2 A. Yes, sir.

3 Q. Go ahead.

4 You also reviewed the 2007 Costello article
5 that concluded that the explanted polypropylene did
6 undergo degradation while in vivo. Do you remember
7 that article?

8 A. Would you show it to me? I believe they
9 fixed that in formaldehyde, too, didn't they, sir?

10 Q. Do you remember it? I'm not sure I have it.
11 You testified at your deposition that you reviewed it.
12 Do you remember?

13 A. Yes, I believe it was fixed in formaldehyde,
14 too, sir.

15 Q. And they concluded that there was
16 degradation?

17 A. By virtue of looking at the fibers that
18 cracked, my opinion has always been that that was the
19 protein formaldehyde polymer. They didn't identify
20 polypropylene as the cracked material.

21 Q. So you disagree with these authors as well?

22 A. I do by virtue of the fact that they didn't
23 understand all of the facts of their article.

24 Q. Okay.

25 You also looked at the Clave article. 2010

1 Clave article. Conclusion, these studies showed the
2 polypropylene meshes undergo degradation while in vivo.
3 That means in the body?

4 A. Yes, it does.

5 Q. These were actually mesh that were taken out
6 of the women's bodies, correct?

7 A. That's right, a hundred of them, a hundred
8 explants.

9 Q. Hundred explants, and they concluded that
10 there was degradation, and you disagree with those
11 authors?

12 A. They concluded that there they could make no
13 determination whether there was degradation or not at
14 the last of this particular article.

15 Q. Page 8?

16 A. If you go to the last of the article.

17 Q. Okay.

18 A. And read the conclusions. There is not
19 enough evidence to show there was oxidation. And
20 they're concerned about the fact that there are esters
21 present, which is true from triglycerides, that show
22 carbonyl peaks, and they can't distinguish whether the
23 carbonyl peaks are from oxidation or triglycerides.

24 Q. Okay.

25 A. But that particular article, a hundred

1 explants could not prove that Ethicon's material
2 oxidized.

3 Q. Let's look at the conclusion.

4 For transvaginal surgery, clinical experience
5 indicates the use of low density large pore implants
6 emitted from a monofilament to facilitate tissue
7 integration and decrease the inflammatory reactions.

8 This study, however, brings into question the
9 prevailing understanding of polypropylene as inert when
10 used in vaginal surgery for pelvic floor repair
11 procedures. Right?

12 A. Yes, sir.

13 Q. Is that what you're basing that on?

14 A. No, sir. They're various sections in there
15 about VSC analysis, and FTIR analysis and several
16 hypotheses persist concerning the nature of
17 polypropylene *in vivo* degradation.

18 That's the part I'm talking about.

19 Q. Several hypotheses persist concerning the
20 nature of polypropylene *in vivo* degradation, that
21 sounds like they think there is *in vivo* degradation?

22 A. We're just taking words out of there. We're
23 going to have to do a lot of reading here before I get
24 to what I want to you see.

25 Q. Large detachments and hematomas are one of

1 the characteristics of the vaginal route and ultimately
2 result in the massive accumulation of blood derived
3 fatty acids. The diffusion of organic molecules into
4 the polymer especially esterified fatty acids or
5 cholesterol may be a cause of the polymer structured
6 degradation.

7 A. That's absolutely false.

8 Q. You disagree with what --

9 A. Absolutely. Because what those polyesters
10 do, they're plasticizers. And as a matter of fact,
11 that's very well known chemistry. If you want to see
12 that, you can look under a manuscript, Polypropylene A
13 to Z. It will describe to you in there that chemistry
14 where polypropylene is plasticized by that. And that
15 article did not say, did not conclusively conclude that
16 polypropylene is degraded, although it implies it from
17 its title. It's an unfair title, in my opinion.

18 MR. CARTMELL: Thank you, that's all I
19 have.

20 THE WITNESS: You're welcome, sir.

21 THE COURT: Mr. Noteware.

22 REDIRECT EXAMINATION

23 BY MR. NOTEWARE:

24 Q. Dr. Thames, have you ever testified before on
25 behalf of Ethicon, Inc.?

1 A. No.

2 Q. Have you ever testified before on behalf of
3 Johnson & Johnson?

4 A. No, sir.

5 Q. When you got the samples, and you felt that
6 there was a need to clean them -- well, first of all,
7 what is ASTM?

8 A. The American Society of Testing Materials.

9 Q. And was there a protocol that was set out in
10 the ASTM as to how to clean off this protein
11 formaldehyde cross link polymer?

12 A. No, there was not.

13 Q. So you had to do something on your own. You
14 had to make up your own protocol?

15 A. I did.

16 Q. And did you make up a protocol that you
17 thought was scientifically intellectually valid in an
18 effort to clean off this cross link polymer from the
19 fiber, so that you could examine the fiber?

20 A. I did. If I didn't get the cross link
21 polymer off, how could I examine the fiber?

22 Q. Now, Mr. Cartmell spent some time talking to
23 you, and asking you, do you have any articles that say
24 that this reaction between protein and formaldehyde
25 would occur over the polypropylene.

1 Would this same reaction occur whether or not
2 there was any other polymer around? Do you have to
3 have it being around polypropylene in order to have
4 this reaction?

5 A. Absolutely not. It will occur anywhere
6 around anything.

7 Q. So the fact that there may not be an article
8 that says this reaction is around polypropylene, is
9 that proof that your thesis and your theory is wrong?

10 A. No, sir, it is not.

11 Mine is not a theory, it's fact.

12 Q. All right. What is Teflon?

13 A. Teflon is a nonstick free agent. I think
14 we've all heard of it. It's a material that our frying
15 pans are made out of, so our eggs and our bacon won't
16 stick. Well, eggs primarily. Bacon has enough fat it
17 doesn't need that. But it's nonstick surface, nothing
18 will adhere to it.

19 Q. How about this PVDF?

20 A. Polyvinylidene fluoride.

21 Q. You heard Mr. Cartmell talk about that and
22 talk it in about the Celine Mary article?

23 A. Right.

24 Q. And saying, that well, they didn't find any
25 of the, the -- they didn't say that, but they said

1 there was nothing covering it, and there was something
2 covering the polypropylene.

3 Is there an explanation for that, a chemical
4 explanation for that?

5 A. In my opinion, yes, sir. May I step down and
6 use the white board?

7 Q. Why don't you do so. You don't need this up
8 here, do you, what's already on here?

9 A. No, sir.

10 Q. I hope that means something to you?

11 A. Yes, sir, it does. It's all in the
12 chemistry, Mr. Noteware.

13 Q. All right. Why don't you tell us what that
14 means?

15 A. Well, I've drawn the basic structure of
16 polypropylene, that's the unit of polypropylene that we
17 talked about here today. And then this is
18 polyvinylidene difluoride.

19 Q. That's the other?

20 A. That's the other fiber that's made from this
21 product right here.

22 And you notice it has two fluorine atoms on
23 this carbon rather than a methyl and a hydrogen in a
24 polypropylene.

25 And then this is Teflon. Teflon has four

1 fluorine atoms on the two carbons. What we're looking
2 at here is a completely nonstick material that
3 everybody in this room knows things won't stick to.

4 We also know that materials will adhere to
5 polypropylene. We've shown that.

6 This is a hybrid structure between that
7 material and that material. And therefore because of
8 its polarity, and because of these two fluorine atoms,
9 it's going to be less likely for any materials to
10 adhere, and polypropylene, but not quite as good as
11 Teflon.

12 Q. Does it surprise you then that the -- this
13 new cross link polymer that we're talking about did not
14 adhere to the PVDF, but it did to the other?

15 A. It wouldn't surprise me that it didn't adhere
16 to it. It would still encase it, but it may well not
17 adhere to it, but it definitely will adhere to
18 polypropylene, because of its chemical structure.

19 Q. Again, in those same pictures that showed the
20 circumferential cracking --

21 A. Yes, sir.

22 Q. -- around it. And is that subject to the
23 same thing as you're talking about when you're talking
24 about your arm and how -- why it is more proof
25 positive, in your mind, that that's new encasements

1 that's there, that hardened encasement?

2 A. Yes, sir.

3 Q. All right. Back to the Celine Mary article.

4 Let's talk about the Clave's article. Mr. Cartmell
5 didn't --

6 MR. NOTEWARE: May I approach the
7 witness, Your Honor?

8 Q. -- he didn't tell us all that was in that
9 article. Now, you were trying to get to him.

10 Why don't you read to the Jury what it says
11 there that I've got highlighted.

12 A. This is page 206 in the Clave article that
13 talks about comparative analysis of 100 explants, and
14 it says, this is under Polypropylene implants are
15 altered in vivo. Several hypotheses concerning the
16 degradation of polypropylene are described below.

17 Editorialize, it's a hypothesis, it' not a
18 fact.

19 Q. Okay.

20 A. None of these, particularly direct oxidation,
21 could be confirmed in this study.

22 Q. None of these, particularly oxidation.

23 A. Could be confirmed in this study.

24 Q. Mr. Cartmell didn't mention that, did he?

25 A. No, sir. That's what I was trying to get to

1 but didn't manage to make it there.

2 Q. Does Ethicon, Inc., have any polymer
3 scientists employed, to your knowledge?

4 A. I don't know, sir.

5 Q. Okay. When they were talking about that
6 thesis and the article that said the eight years, you
7 indicated that there was something else that you wanted
8 to say.

9 A. Well, I noticed in one of the lab notebooks
10 that the -- it was pointed out that Dr. Guidoin, who
11 gave up his explants for them to look at, that they
12 were eight years old. And in order for them to be
13 eight years old, and to not be petrified, or putrid, so
14 forth, they would have had to be been fixed in protein
15 or with formaldehyde, and would have had to have been
16 encased by the same material that we've been talking
17 about here today.

18 There is no way they could have been eight
19 years old.

20 Also, he points out in there that this
21 possible oxidation, and I believe he talks about an
22 absorption peak at 1650 reciprocal centimeters. That
23 peak is not consistent with oxidation of the C double 1
24 O, it's a protein. Although he makes the statement
25 that there's no evidence of protein, it's a protein.

1 That is a protein peak.

2 So he has missed it.

3 Q. Now, we saw earlier today the spectra, and it
4 was of protein, and how there are specific fingerprints
5 that indicate that something is protein.

6 A. Yes, sir.

7 Q. And is the reciprocating centimeters,
8 whatever those are, is that one of those peaks?

9 A. Yes, sir. It's an energy level where
10 proteins absorb energy. Yes, sir.

11 Q. When the explant was cleaned, were chemicals
12 used to clean -- and this is by Dr. Ong?

13 A. Yes, sir.

14 Q. Following your protocol?

15 A. Yes, sir.

16 Q. Were chemicals used to clean the explant?

17 A. Yes, sir.

18 Q. If you were to go now and test the solution,
19 or the residue that was pulled off, or was -- I don't
20 know how you talk about it, I'm afraid I'm not a
21 chemist as you can --

22 A. It's the waste.

23 Q. The waste. If you were to go over and
24 examine that, would that give you any meaningful data
25 at all?

1 A. No, sir. I wanted to look at the fiber
2 itself, not what was encasing it. I've already proven
3 by FTIR spectroscopy what's encasing it, and by virtue
4 of the chemical reactions that take place, which is
5 extremely well known, 60 years. So I wanted to look at
6 the fiber itself, see if it showed any signs of
7 degradation.

8 Q. So when you looked at the fiber itself did
9 you see any signs whatsoever of oxidation?

10 A. No, sir.

11 Q. And if there weren't any oxidation, there
12 wouldn't be any degradation?

13 A. That's correct, sir, not by oxidation.

14 Q. You heard all of the questions that were
15 asked to you by Mr. Cartmell?

16 A. Yes, sir.

17 Q. Have they changed in any way your opinion,
18 sir, that there was no degradation that was existent
19 with regard to the mesh that was explanted from
20 Ms. Batiste?

21 A. No, sir.

22 Q. All of the questions, and all of the articles
23 that Mr. Cartmell has brought up, have they in any way
24 changed your opinion that there was no oxidation of the
25 mesh that was taken from Ms. Batiste?

1 A. No, sir.

2 Q. Has it in any way changed your opinion, sir,
3 that there was nothing that impacted the functionality
4 of the mesh that was in Ms. Batiste?

5 A. From a chemical perspective, no, sir,
6 certainly not.

7 MR. NOTEWARE: I have no other
8 questions.

9 MR. CARTMELL: Real briefly.

10 RECROSS-EXAMINATION

11 BY MR. CARTMELL:

12 Q. You're not here to give any opinion about
13 whether or not the TVT-O PROLENE mesh, when it is
14 implanted in a woman, ropes or curls or loses
15 particles, correct?

16 A. No, sir.

17 Q. Or whether or not it has sufficient porosity
18 or is too heavy to be placed in a woman's pelvis,
19 correct?

20 A. That's not my field, sir.

Q. Thank you. I have nothing further. Thanks.

22 A. Thank you.

23 MR. NOTEWARE: One quick one, Judge,
24 maybe two, but no more than that.

25 REDIRECT EXAMINATION

1 BY MR. NOTEWARE:

2 Q. You indicated it wasn't your field. Did you
3 notice Dr. Jordi was able to talk about inflammation.
4 Is that part of polymer chemistry, sir?

5 A. Not part of what I can talk about, no, sir.

6 MR. NOTEWARE: Then I have no further
7 questions.

8 THE COURT: Anything further?

9 MR. CARTMELL: No.

10 THE COURT: May this witness be
11 released?

12 MR. CARTMELL: Yes, Your Honor.

13 THE WITNESS: Thank you, sir, I
14 appreciate it.

15 Ladies and gentlemen, we'll be in recess
16 until 9:15 a.m. Monday. Remember my previous
17 instructions. Do not search for, view, listen for any
18 matter in any way connected with this case, or the
19 issues presented in this case.

20 Thank you, we're in recess.

21 (Jury out)

22 THE COURT: All right, what's our
23 scheduling look like now?

24 MR. NOTEWARE: Dr. Anhalt obviously
25 didn't get on today, he can't be available Monday. He

1 is our last live witness, I believe, Judge, so we have
2 depositions that we can put on.

3 THE COURT: All right.

4 MR. NOTEWARE: I honestly don't know how
5 long they are.

6 MR. GAGE: Four to six hours, we're
7 going to work with my team this weekend, see if we
8 can't get that much closer to four, if not less than
9 four.

10 MR. NOTEWARE: So what I suggest, we're
11 going to start obviously Monday morning, let's do as
12 much of the video deposition as we can, and then work
13 on Monday afternoon on the charge. And then Tuesday
14 we'll finish Dr. Anhalt, and I think we'll be done,
15 Judge.

16 They have -- they have the right to call
17 rebuttal witnesses, I will grant them that right,
18 Judge.

19 MR. CARTMELL: Thank you.

20 MR. NOTEWARE: You're welcome.

21 THE COURT: I want y'all to send me,
22 email me your proposed charges. I want to -- so I can
23 work on them remotely.

24 Can you do that? Just have somebody email
25 them to me.

MR. NOTEWARE: Do we have your email address, Judge.

THE COURT: I'll be happy to. Do you have email, Mr. Noteware?

MR. NOTEWARE: My client is here, Your Honor, I would appreciate the Court, please, please.

THE COURT: I don't want anybody to get the wrong opinion. Mr. Noteware and I have known each other for three or four years. For three or four decades.

MR. NOTEWARE: Closer to it, Judge.

THE COURT: And this is not the first time we go back and forth.

MR. NOTEWARE: I don't hold it against you, Judge.

THE COURT: And I don't hold it against you either, Mr. Noteware. KMolberg@DallasCourts.org. And I need those as soon as I can get them and you can send me revisions. This is not an invitation to talk about the case generally.

MR. NOTEWARE: No, this would be just a hardcore, like we would file something. I don't think we ought to be arguing anything.

THE COURT: I want them in Word or WordPerfect format and I want you to copy your

1 opponents when you send it. I need them as quickly as
2 possible. We're doing a complete email boot on our
3 server, I need them before noon Sunday.

4 I would prefer to have them tonight.

5 Anything else we need to discuss?

6 MR. CARTMELL: No, Your Honor.

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8 (Continued to March 31, 2014)

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1 THE STATE OF TEXAS

2 COUNTY OF DALLAS

3 I, SHARRON RODRIGUEZ RANKIN, Official Court
4 Reporter in and for the 160th Judicial District Court
5 of Dallas County, State of Texas, do hereby certify
6 that the above and foregoing contains a true and
7 correct transcription of all portions of evidence and
8 other proceedings requested in writing by counsel for
9 the parties to be included in this Volume of the
10 Reporter's Record in the above styled and numbered
11 cause, all of which occurred in open court and or in
12 chambers and were reported by me.

13 I further certify that this Reporter's Record of
14 the proceedings truly and correctly reflects the
15 exhibits, if any, admitted, tendered in an offer of
16 proof or offered into evidence.

17 WITNESS my official hand this the 28th day of
18 March, 2014.

19 /S/

20 SHARRON RODRIGUEZ RANKIN
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Expiration Date: 12-13-14
23 160th District Court
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Dallas, Texas 75202
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